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Honesty Balanced Perspectives
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Manitoba
April 2006

OFFICE OF THE AUDITOR GENERAL

Audit of the Pharmacare Program
Manitoba Health

As a leader in promoting enhanced accountability of government to the citizens of Manitoba, the Office of the Auditor General will contribute to greater public trust and confidence in the institutions of government.

Vision

As a leader in promoting enhanced accountability of government to the citizens of Manitoba, the Office of the Auditor General will contribute to greater public trust and confidence in the institutions of government.

Mission

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government accountability information;
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the operational performance of government.

Values

IN INTERPERSONAL RELATIONSHIPS

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Office of the Auditor General
500 - 330 Portage Avenue
Winnipeg, Manitoba R3C 0C4

April 2006

The Honourable George Hickes
Speaker of the House
Room 244, Legislative Building
Winnipeg, Manitoba
R3C 0V8

Dear Sir:

I have the honour to transmit herewith my report on the *Audit of the Pharmacare Program, Manitoba Health* to be laid before Members of the Legislative Assembly in accordance with the provisions of Section 28 of The Auditor General Act.

Respectfully submitted,

Jon W. Singleton, CA•CISA
Auditor General

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The Province of Manitoba's Provincial Drug Program (Pharmacare) was developed to protect residents of Manitoba from financial hardships resulting from expenses for prescription drugs. Pharmacare provides one of the most comprehensive drug benefit programs in Canada, in terms of universality of inclusions and citizen's drug costs.

Pharmacare has become the fastest growing cost in the Manitoba Health Care System, with almost $195 million spent in the year ending March 31, 2005, more than double that of $85.6 million for the year ending March 31, 2000. In 2004, the Minister of Health voiced concern in the media over the continuing trend of cost escalation of the program, and cautioned that the continued viability of the program in its current form, may become unsustainable if the trend continues.

In our audit of Pharmacare, we identified many benefits of Pharmacare. However the focus of Manitoba's Department of Health (Manitoba Health) has been on day-to-day operation and delivery of the Pharmacare program. Manitoba Health has not sufficiently explored all avenues available to improve the efficiency and effectiveness of Pharmacare and to contain the cost growth of the program.

In 2004/05 Manitoba Health increased the deductible required to be paid by a person in Manitoba prior to becoming eligible for coverage under Pharmacare. It appears that this increase in the deductible had the effect of slowing the year-to-year rate of growth in the cost of the program from 14.9% in 2003/04 to 5.2% in 2004/05.

Manitoba Health has a computerized Pharmacare management system that is one of the most comprehensive in use in Canada. It is linked to all pharmacies in Manitoba and records and assesses prescriptions at the time they are dispensed. However, that information-rich database system has not been utilized to provide valuable information on drug costs and usage, nor to measure the overall performance of Pharmacare.

We were pleased to see that Manitoba Health has comprehensive procedures in place to assess drugs for selection and then listing on the Manitoba Drug Benefit and Interchangeability Formulary (Formulary). However after the initial analysis and listing of the drugs, we noted that there are inadequate processes for reassessing the drugs on the Formulary for cost effectiveness and therapeutic benefits.

Further, Manitoba Health needs to collaborate with pharmacists, prescribing physicians, national institutions and drug manufacturers in order to implement new strategies which will improve the cost effective delivery of the program.

I am encouraged by the cooperation we received from Manitoba Health during our audit and by their acceptance of our recommendations with a commitment to review and address them in a timely manner.

JW Singleton

Jon W. Singleton, CA•CISA

1.0 Executive Summary

In collaboration with seven other legislative offices in Canada, the Manitoba Office of the Auditor General (OAG) conducted an audit of the Province's Pharmacare Drug Program (Pharmacare) using common audit objectives and criteria. The overall purpose of the audit was to assess whether the Province has a cost effective program for managing Pharmacare and whether it is adequately reporting its performance to the Legislative Assembly.

The following objectives were agreed to by all jurisdictions as the primary focus of an audit of Pharmacare:

- To assess whether Manitoba's Department of Health (Manitoba Health) had adequate procedures in place to manage the performance of Pharmacare;
- To assess whether Manitoba Health had adequate procedures in place to ensure resources were managed with due care for cost effectiveness in relation to Pharmacare;
- To assess whether Manitoba Health monitored the quality and relevance of drug use and encouraged appropriate and economical prescribing and dispensing practices in relation to Pharmacare; and
- To assess whether there was adequate reporting on Pharmacare's performance.

The audit covered the fiscal year ending March 31, 2004 and was conducted between June 2004 and June 2005. Our audit was performed in accordance with the standards for value-for-money auditing in the public sector recommended by the Canadian Institute of Chartered Accountants, and accordingly included such tests and other procedures as we considered necessary in the circumstances.

Pharmacare is a universal, comprehensive, prescription drug benefit program for any Manitoban, regardless of age, who meets the deductible cost criteria for prescription drug costs. Manitoba Health has had some form of drug benefit program since 1971. Since 1996, Manitoba Health has had a provincial drug program, with eligibility and benefits determined by a person's family income and prescription costs incurred. The objective of Pharmacare is to protect residents of Manitoba from financial hardships resulting from expenses for prescription drugs as provided for in *The Prescription Drugs Cost Assistance Act and Regulations*.

Pharmacare is managed within Manitoba Health, by the Provincial Drug Programs Unit (PDP). PDP also maintains the Manitoba Drug Benefits and Interchangeability Formulary (Formulary), the program approved listing of drugs eligible for benefits under Pharmacare. The Formulary listing is available to the public on Manitoba Health's internet website.

The Manitoba Drugs Standards and Therapeutics Committee (MDSTC) is an independent review committee which reviews all drugs prior to placement on the Formulary. MDSTC makes recommendations on drug interchangeability and on the therapeutic and economic value of drug benefits. The Formulary is updated, via a *Manitoba Drug Benefits and Interchangeability Formulary Amendments Bulletin* (Bulletin) approximately every three to four months on the Manitoba Health website and is then sent to pharmacies and physicians.

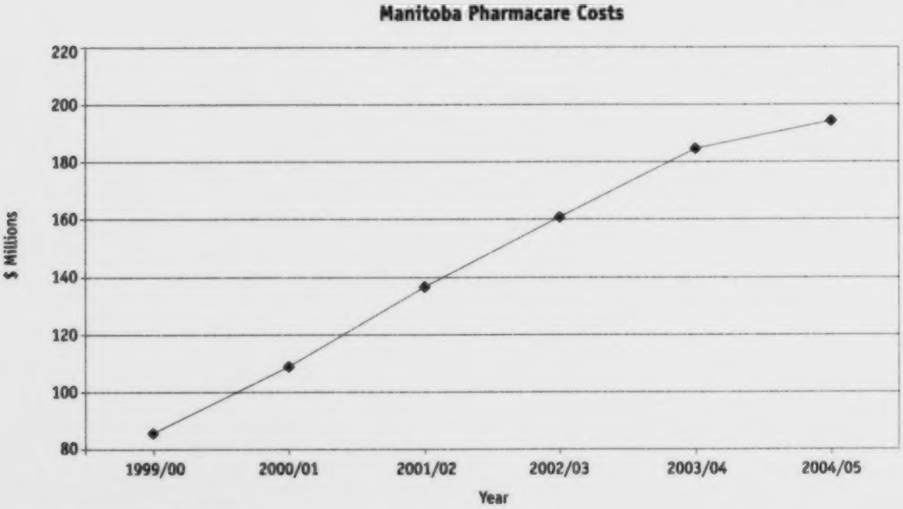
Manitoba Health operates a computerized system called the Drug Program Information Network (DPIN) which links Manitoba Health and all pharmacies and emergency rooms in the province for the purpose of maintaining a central database for prescription drugs and the related billing.

ESCALATING PHARMACARE COSTS

Total drug costs for all of Manitoba Health's provincial drug programs increased from $205 million in 2000/01 to $327 million in 2004/05. Pharmacare costs have been approximately 53% to 60% of the total provincial drug program costs over this time period.

In the six year period from April 1, 1999 to March 31, 2005, Pharmacare expenditures have more than doubled, increasing from $85.6 million to $194.4 million as shown in **Figure 1**.

FIGURE 1



Source: Manitoba Health

Although all other provinces have experienced cost escalation, Manitoba has experienced higher average cost escalation than most other jurisdictions. While other jurisdictions in Canada have incurred an average increase of 20% per year since 1999, Manitoba has experienced an average increase of 25% per year. General factors typically identified as the primary reasons for the cost increases nationally (as highlighted in **Section 3.3**) are:

- Changes in Patent Law;
- An aging population;
- Advances in medical care with drug therapy;
- Aggressive marketing by drug companies to doctors and patients promoting the use of newer and more costly drugs;

- Lack of aggressive management of the provincial Formulary to ensure the most cost effective drugs are used as the first line of treatment;
- Increases in the cost of drugs and dispensing fees being charged; and
- Cost containment practices by private insurers.

Manitoba Health officials advised that they have not analyzed how these factors may have affected the cost of Pharmacare.

OAG identified the following factors as contributing to the increase in expenditures in Pharmacare between April 1, 1999 to March 31, 2004 (up to March 31, 2005 shown in brackets) as follows:

Comprehensiveness of Program

- Manitoba's Pharmacare provides one of the most comprehensive drug benefit programs in Canada, in terms of universality of inclusions and citizen's drug costs. In the report, *Drug Expenditure in Canada 1985 - 2004*, the Canadian Institute for Health Information (CIHI) found that in 2002, the Province of Manitoba paid 50.1% of prescription drug expenditures in Manitoba. This was the second highest coverage in Canada;

Increased Eligibility

- Since 1999, the number of Manitoba families receiving Pharmacare benefits increased from 62,519 to 88,988 families, or by 42% (40% up to March 31, 2005);

Increased Prescriptions

- The number of Pharmacare prescriptions processed annually has increased from 1.8 million for the year ended March 31, 2000 to 3.0 million for the year ended March 31, 2004, or 65.5% over this five year period (70% up to March 31, 2005);

Increased Drug Costs

- The average drug cost per prescription has increased from $43.95 for the year ended March 31, 2001 to $51.26 for the year ended March 31, 2004, or 16.6% over this four year period (18.5% up to March 31, 2005);

Increased Dispensing Fees

- Dispensing fees account for approximately 17% of Pharmacare costs, which for the 2003/04 fiscal year would amount to over $31 million (over $33 million for 2004/05);
- Manitoba's overall average dispensing fee has risen from $7.58 to $10.06 or 32.7% over the four year period of March 31, 2001 to March 31, 2004 (43.5% over the five year period ending March 31, 2005). There is no limit placed on the dispensing fee that a pharmacist may charge Pharmacare. We noted an example where a prescription for a $7,320 drug cost incurred a $300 dispensing fee;
- Based on a sample of 20 patented drugs sold in Canada, Manitoba paid the highest average dispensing fee; and
- We calculated the actual dispensing fees paid in Manitoba for a sample of 20 specific drugs in 2002/03. The total cost of those 20 drugs to

Pharmacare for 2002/03 was $23.3 million. Dispensing fees for those 20 drugs accounted for $4.1 million or 17.6% of that cost.

All provincial and federal jurisdictions have indicated they are aware of the rapid growth in the cost of the pharmacare/drug programs and have identified the containment of the rapid increase of the cost of prescription drugs as a critical success factor in maintaining the financial viability of the national health care system.

In 2004/05, Manitoba Health attempted to contain the continuing cost increases in Pharmacare by raising the deductible for the program. It appears that this contributed to slowing the year-to-year rate of growth in the cost of the program from 14.9% in 2003/04 to 5.2% in 2004/05.

Manitoba Health has taken steps to analyze best practices in pricing and attempted to address pricing policy issues by participating in, and reviewing, numerous studies on prices of medicines performed by the Patented Medicine Prices Review Board and other bodies. We were informed that the results of those studies were used in internal discussions on pricing strategy. Although a Pricing Strategy paper dated December 20, 2004 was prepared by Manitoba Health to address mark-ups and price changes, this document was not formally approved and finalized.

MAIN CONCLUSIONS

In general, we believe that Manitoba Health has not sufficiently explored all avenues available to improve the cost efficiency and effectiveness of Pharmacare, in order to manage the cost and growth of the program. While Manitoba Health has indicated that they have implemented some cost containment measures and implemented a federal/provincial/territorial Common Drug Review (CDR) process in December 2004, we are concerned that Manitoba Health has not sufficiently utilized its abundance of data in the Drug Program Information Network to analyze specific factors impacting Pharmacare costs in order to effectively manage and contain expenditures.

The following are the key conclusions for each of the four audit objectives. Our detailed report outlines the specific observations and conclusions. Recommendations for each of the audit objectives are detailed in **Section 8.0**.

Program Management (Section 4.0)

Manitoba Health did not have adequate procedures in place to manage the performance of Pharmacare, which could have included:

- A rigourous planning process;
- A performance measurement system;
- A performance evaluation process; and
- A system for proactively monitoring compliance with legislation, regulations and policies of Pharmacare.

As a result, decisions were made about changes to Pharmacare in the absence of a clearly articulated and documented policy framework.

Not having these program management components in place could potentially have serious long-term financial implications in an era when program costs appear to pose a fundamental threat to the sustainability of Pharmacare.

Drug Selection and Cost (Section 5.0)

Although Manitoba Health had processes for assessing which drugs to place on its Formulary, it did not have adequate processes in place to ensure Pharmacare was managed with due care for cost effectiveness, as follows:

- No analysis was performed by Manitoba Health on the actual cost savings of the drugs after being added to the Formulary as compared to the proposed cost savings.
- Drugs listed on the Formulary were assessed for proposed pharmaceutical and cost effectiveness (economic assessment) by an independent advisory committee prior to their placement on the Formulary. Some of that economic assessment was provided by the drug companies in their submission for their drugs to be added to the Formulary.
- Although we found that policies and procedures were in place for the use of generic drugs and lowest cost pricing of drugs in the Formulary, we noted opportunities to enhance drug costing and the financial sustainability of Pharmacare through the use of Referenced Based Pricing and/or bulk purchasing. Manitoba Health could have potentially realized additional cost savings of over $2.6 million in 2002/03 on two drugs alone if Reference Based Pricing had been used for those two drugs.
- In addition to the costs of the drugs themselves, dispensing fees were charged by pharmacies and reimbursed by Pharmacare. Prior to 1994, Pharmacare had a regulated limit or cap on dispensing fees. In 1994, this cap was lifted, and the dispensing fees have since been determined by the market place.
    - The uncontrolled cost of dispensing fees has added substantially to the increasing costs of Pharmacare. In a review of individual dispensing fees paid to pharmacies, we found they ranged from under $6 at a large box retailer to over $12 at certain retail pharmacy chains.
    - Manitoba Health estimated that dispensing fees account for 17% of Pharmacare costs, which for the 2004/05 fiscal year would amount to over $33 million.
    - Manitoba's overall average dispensing fee of $9.10 in 2002/03, was the highest of all jurisdictions surveyed at that time.
    - Average dispensing fees for Pharmacare have risen from $7.58 to $10.88 or 43.5% in the 5 years from 2000 to 2005.

Physician Prescribing Practices and Monitoring of Drug Use (Section 6.0)

Overall, Manitoba Health requires significant improvement in their monitoring of the quality and relevance of drug use, and their encouragement of appropriate and economical prescribing and dispensing practices. In particular:

- Manitoba Health did not monitor physician's prescribing practices, nor did it actively promote the most appropriate and economical prescribing practices to physicians through the communication of best practice information. As a result, Manitoba Health had limited means to attempt to control program costs through influencing physicians' prescribing practices.

- Prescription drug utilization has been identified as a driver of prescription costs. The DPIN system currently provides pharmacists with a six month history of a person's prescriptions, which a pharmacist may review to assess concerns regarding a patient's concurrent prescription drug use at the time of dispensing. However, Manitoba Health could better analyze annual and longer trend information from DPIN to determine potential health risks to drug recipients, such as prescriptions for excess drugs, or narcotic and controlled drugs. Polypharmacy is defined as a situation when an individual is taking six or more different medications at the same time. While there are some instances where multiple medications are required for proper disease management, there is evidence that people taking six or more medications are at an increased risk of medication related adverse events. Some examples of drug use over a one year period are as follows:
    - In 2003, information from Manitoba Health indicated that 49,164 cases were reimbursed by Pharmacare where individuals were receiving more than six different drugs; 7,213 cases were reimbursed by Pharmacare where individuals were receiving more than 15 different drugs; and 6 cases were reimbursed by Pharmacare where individuals received more than 50 different drugs;
    - In 2003, there were 27,496 cases reimbursed by Pharmacare where people over 65 years of age received more than seven different drugs; and
    - In 2003, there were 101 cases reimbursed by Pharmacare where people received a narcotic or controlled drug and used four to six physicians and four to six pharmacies to obtain drugs.

Reporting to the Legislature (Section 7.0)

Manitoba Health's 2003/04 Annual Report, which reported information on Pharmacare, was inadequate in providing sufficient information to enable the reader to draw conclusions on how well Pharmacare is functioning nor did it provide transparent accountability information. We also noted that the information on Pharmacare, which was provided in Manitoba Health's 2003/04 Annual Report, was not consistent with the CCAF Performance Reporting Principles and only partially fulfilled the *Departmental Annual Reports Instructions* issued by the Department of Finance.

2.0 Introduction

2.1 INITIATION OF AUDIT

During 2003, the Canadian Council of Legislative Auditors (CCOLA) – Health Study Group (HSG) decided to undertake a collaborative audit of Pharmacare in their jurisdictions, using common audit objectives and criteria. Manitoba participated through the performance of this audit.

In just six years, Manitoba's Pharmacare Program (Pharmacare) expenditures have more than doubled - increasing from $85.6 million in 1999/00 to $194.4 million in 2004/05. Since 1999, the number of Manitoba families receiving Pharmacare benefits has increased by 40% from 62,519 to 87,029.

Manitoba's Department of Health (Manitoba Health) and the Departments of Health in all other provincial and federal jurisdictions have indicated they are aware of the rapid growth in the cost of the pharmacare/drug programs and have identified the containment of the rapid increase of the cost of prescription drugs benefit programs as a critical success factor in maintaining the financial viability of the national health care system. The Minister of Health was quoted in the Winnipeg Free Press on March 19, 2004 as saying that *"if Pharmacare continues to grow at the present rate, in 10 years the cost will be more than the City of Winnipeg's budget"* ($700 million).

2.2 AUDIT AUTHORITY

The audit was carried out under the authority of Section 14(1) of *The Auditor General Act* which states:

> *"In carrying out his or her responsibilities under this Act, the Auditor General may examine and audit the operations of a government organization with regard to any of the following matters:*
>
> *a) whether financial and administrative provisions of the Acts, regulations, policies and directives have been complied with;*
> *b) whether public money has been expended with proper regard for economy and efficiency;*
> *c) whether the Assembly has been provided with appropriate accountability information;*
> *d) whether the form and content of financial information documents is adequate and suitable."*

2.3 OBJECTIVES, SCOPE AND APPROACH

2.3.1 Audit Objectives

Based on preliminary review and analysis, Manitoba and the seven other legislative audit offices participating in the collaborative audit agreed on a set of audit objectives as the primary focus of an audit of Pharmacare. This report represents the first phase of our work in auditing Pharmacare. We are reporting on four of the nine audit objectives; a future report will deal with remaining objectives. The four objectives covered in this report are:

- To assess whether Manitoba Health had adequate procedures in place to manage the performance of Pharmacare (**Program Management**).
- To assess whether Manitoba Health had adequate procedures in place to ensure resources were managed with due care for cost effectiveness in relation to Pharmacare (**Drug Selection and Cost**).
- To assess whether Manitoba Health monitored the quality and relevance of drug use and encouraged appropriate and economical prescribing and dispensing practices in relation to Pharmacare (**Physician Prescribing Practices and Monitoring of Drug Use**).
- To assess whether there was adequate reporting on Pharmacare's performance (**Reporting to the Legislature**).

A glossary of terms is provided in **Appendix A**.

2.3.2 Audit Scope and Approach

We defined the scope of our audit as Manitoba's Pharmacare Program (Pharmacare) which is responsible for the dispensing of drugs to individuals through retail pharmacies. Our audit did not cover the other significant drug costs which are paid for by Manitoba Health for drugs provided to patients in hospitals and Personal Care Homes (PCHs); and those paid for by the Department of Family Services for people on social assistance.

The audit covered the fiscal year ending March 31, 2004. Our work was conducted between June 2004 and June 2005.

The audit objectives and audit criteria used were jointly developed by the legislative audit offices in Canada (**Appendix B**).

We interviewed individuals within Manitoba Health, responsible for the management and administration of Pharmacare, reviewed documentation, and requested and reviewed numeric and financial data from Manitoba Health. In addition, we reviewed the Drug Program Information Network (DPIN), a computerized system which links Manitoba Health and all pharmacies and emergency rooms in the province for the purpose of maintaining a central database for prescription drugs and the related billings maintained by Manitoba Health.

Our audit was performed in accordance with the standards for value for money auditing in the public sector recommended by the Canadian Institute of Chartered Accountants, and accordingly included such tests and other procedures as we considered necessary in the circumstances.

3.0 Background

Facts About the Manitoba Pharmacare Program

- Pharmacare is an income based program, with a minimum deductible of $100 and no maximum benefits.
- There is a one-time enrollment process available. Manitoba residents do not have to apply for benefits yearly.
- There is a listing of drugs eligible for Pharmacare benefits (the Formulary). There are over 5,000 eligible drugs on the Formulary.
- There is an independent committee of experts that reviews drugs on the Formulary.
- The Drug Program Information Network (DPIN) assesses claims and tracks prescriptions and is accessible to all pharmacists, but not by physicians from their offices.
- Differences between Pharmacare and other drug programs in Canada include:
    - Which drugs are covered;
    - The cost of drugs covered;
    - Who is eligible for coverage; and
    - The payment of a premium.

See **Appendix C** for a comparison of Canadian Pharmacare Plans.

3.1 DESCRIPTION OF PHARMACARE

In Manitoba, Pharmacare is a universal, comprehensive, prescription drug benefit program for any Manitoban, regardless of age, who meets the deductible cost criteria for prescription drug costs. Since 1971, Manitoba has had some form of drug benefit program. Since 1996, Manitoba Health has had a provincial drug program with eligibility and benefits determined by a person's family income and prescription costs incurred. Prior to 1996, Pharmacare was a combination of flat rates and deductibles with seniors having a lower flat rate and lower deductible (30% of each prescription for seniors vs. 40% for all other people).

The objective of Pharmacare is to fund pharmaceutical benefits as provided for in *The Prescription Drugs Cost Assistance Act and Regulations*. The main objective of this Act is to protect residents of Manitoba from financial hardships resulting from expenses for prescription drugs. Eligibility (as defined in legislation) is based on the following criteria:

- Being eligible for Manitoba Health coverage;
- Prescriptions are not paid by other provincial or federal programs;
- Prescription costs are not covered by a private drug insurance program; and

- Eligible prescription costs exceed a person's Pharmacare deductible (see **Appendix D** for calculation of deductible).

Pharmacare is also governed by some parts of *The Pharmaceutical Act* (e.g., the cost of drugs).

3.1.1 Pharmacare Deductible and Benefits

Manitoba citizens do not pay either premiums or a co-payment for their drugs, as do citizens in some other jurisdictions. However, Manitobans are required to pay the first portion of the cost of their eligible prescription drugs each year up to their calculated family deductible amount. This deductible amount for the 2005/06 benefit years is determined as follows:

- A family deductible is based on annual family income and dependants as identified by an indivdual's income tax return. The deductible ranges from 2.44% for total family income of up to $15,000, (with a minimum deductible of $100), to the maximum deductible of 5.25% for total family income greater than $75,000.
- Once a family has reached their deductible, Pharmacare pays 100% of the family's drug costs.

Manitoba's Pharmacare program is different from that of most other jurisdictions (**Appendix C**). Other provinces offer a combination of drug benefit plans which may combine private and public coverage.

In the report, *Drug Expenditure in Canada 1985-2004*, the Canadian Institute for Health Information (CIHI) found that in 2002, the Province of Manitoba paid 50.1% of prescription drug expenditures. As illustrated in **Figure 2**, this percentage was the second highest among all provinces.

FIGURE 2

Prescription Drug Costs Covered by Government Benefit Programs 2002

Jurisdiction	% Coverage
British Columbia	50.6
Manitoba	**50.1**
Quebec	49.5
Saskatchewan	46.4
Alberta	45.7
Ontario	44.9
Newfoundland and Labrador	39.8
Nova Scotia	37.1
Prince Edward Island	34.7
New Brunswick	33.5
Nationally	46.4

Source: *Drug Expenditure in Canada 1985-2004*, Canadian Institute for Health Information (CIHI)

As noted in the CIHI report, *"There is considerable variation, in the level and growth of drug expenditure across the provinces and territories. These variations are influenced by several factors, including differences in provincial drug subsidy programs, variations in the age and sex distributions of provincial/territorial populations, the health needs of targeted populations, and the manner in which health care is delivered (including the balance between institutional and ambulatory care)"*.

In some other Canadian jurisdictions (**Appendix C**), prescription drug cost assistance to residents may be based on criteria such as:

- age (over 65 or under 18 years of age);
- requirement for the individual to be on social assistance;
- coverage for specific disease treatment (e.g., cancer); and
- a requirement for a premium payment to enroll in a provincial pharmacare plan.

3.2 MANAGEMENT AND DELIVERY OF THE PROGRAM

3.2.1 Organizational Structure

Pharmacare is administered within Manitoba Health, by the Provincial Drug Programs Unit (PDP).

PDP also administers the following programs:

- Palliative Care Drug Access Program;
- Personal Care Home Drug Program;
- Family Services Drug Program;
- Exception Drug Status Office; and
- Ancillary Programs which includes: Breast Prosthesis Program, Children's Hearing Aid Program, Senior's Eyeglass Program, Telecommunication Devices, Children's Orthopedic Shoes Program, Infant Contact Lenses, Artificial Eyes, Prosthetic and Orthotic Devices.

Funding for the Personal Care Home Drug Program and Family Services Drug Program are not included in the PDP appropriations.

The 39.5 full-time equivalent employees within PDP consist of:

- 24.5 customer service staff that review and process applications, adjustments and manual claims for the public and pharmacies as well as supporting the mandate of Manitoba Health, the Manitoba Drug Standards and Therapeutics Committee (MDSTC), and enforcing and adjudicating Pharmacare in adherence to legislation and internal policies; and
- 15 administrative and support positions including:
  - Four pharmacists to provide scientific advice and policy support on drug related issues;

- Six analysts to provide statistical, research, and policy recommendations on program related issues; and
- One Executive Director, two managers and two administrative support staff.

3.2.2 Eligible Prescription Drugs

The Manitoba Drug Benefits and Interchangeability Formulary (Formulary) is the provincially approved listing of drugs eligible for benefits under Pharmacare.

The Formulary is divided into three parts:

1. Part 1 includes drug products that are eligible for Pharmacare benefits under all prescribed circumstances;
2. Part 2 includes drug products that are eligible for Pharmacare benefits only when prescribed for under certain terms and conditions; and
3. When a drug is not listed on Part 1 or Part 2, a request for Exception Drug Status (EDS) coverage will be considered under Part 3 for each individual circumstance.

Each drug has a Drug Identification Number (DIN), which is a Health Canada assigned number, using specifications such as the manufacturer, the active ingredient, the strength of ingredient, dosage form (i.e., pill, drops, liquid, etc.), the drug brand/trade name, and the route of administration (i.e., orally, applied to skin, etc.).

As at March 31, 2004, the Formulary contained the following number of DINs:

- 5,290 with no restrictions on reimbursement from Pharmacare (Part 1);
- 341 where there is reimbursement under certain conditions (Part 2); and
- 521 that were reimbursed only under an exception or restricted basis (Part 3).

3.2.3 Pharmacare Process for Adding Drugs to Formulary

The Manitoba Health website outlines a process (*Manitoba Drug Standards and Therapeutics Committee Submission Requirements*) that drug manufacturers need to follow in order to have their drug considered for listing in Manitoba. This was last updated in September 2003.

Manitoba Health's internal process for listing drugs on the Formulary follows *The Prescription Drugs Payment of Benefits Regulation* which was established under *The Prescription Drugs Cost Assistance Act*. The process was outlined in a document called *The Formulary Policy and Procedures*. *The Formulary Policy and Procedures* document also provides guidelines regarding whether the drug is classified as Part 1, 2, or 3 (EDS). The objectives of *The Formulary Policy and Procedures* are to:

- Provide Pharmacare coverage to Manitoba residents for quality pharmaceutical products of proven therapeutic effectiveness;

- Reduce the cost of drug materials; and
- Encourage rational use of prescription drugs.

The drug evaluation and approval process used to determine whether or not a drug should be listed on the Formulary includes the following steps:

- A pharmaceutical company must formally request a drug be evaluated for listing on the Formulary;
- Manitoba Health prepares an evaluation of each drug request submitted and considers information about drug cost, the therapeutic value of the drug, economic impact on the Manitoba Health system and the interchangeability among other similar chemically and therapeutically equivalent drugs already available;
- The MDSTC, comprised of Manitoba pharmaceutical and medical professionals, reviews the proposal from Manitoba Health for changes to the provincial Formulary;
- Subsequent to review by the MDSTC, a recommendation for approval of the drug is forwarded to the Minister of Health;
- Once drugs have received approval from the Minister of Health for addition or deletion from the Formulary, Manitoba Health is responsible for updating the listing of approved drugs on the Formulary; and
- The listing is updated via a *Manitoba Drug Benefits and Interchangeability Formulary Amendments Bulletin* (Bulletin) approximately every three to four months. These Bulletins are posted on the Manitoba Health website and sent to pharmacies and physicians.

3.2.4 Independent Drug Review Committee

MDSTC is the independent review committee which reviews all drugs prior to placement on the Formulary. MDSTC is composed of three physicians and three pharmacists, none of which are employed by Manitoba Health. Committee members make recommendations on drug interchangeability and on the therapeutic and economic value of drug benefits. Nominations for committee membership are provided by the College of Physicians and Surgeons of Manitoba, the Manitoba Medical Association, Manitoba Pharmaceutical Association and the University of Manitoba. The roles and responsibilities of the MDSTC were documented in the terms of reference for the MDSTC dated September, 1998. It also defined the membership:

> *"The Committee shall be comprised of at least six (6) individuals with expertise in the areas defined by the objectives."*

The objectives of MDSTC are:

- To assist Manitoba Health in determining which drugs will be provided to Manitobans by government programs;
- To assist Manitoba Health in determining which drugs and drug products are interchangeable;

- To assist Manitoba Health in assuring that government drug benefits are rational and cost effective; and
- To assist Manitoba Health in addressing other drug utilization issues.

3.2.5 Drug Program Information Network

Manitoba Health operates a computerized system called the Drug Program Information Network (DPIN) which links Manitoba Health and all pharmacies and emergency rooms in the province for the purpose of maintaining a central database for prescription drugs and the related billing.

The DPIN processes over 20 million transactions annually. The DPIN system in Manitoba was one of the first real time systems for linking all pharmacies in a province and providing pharmacists with comprehensive information regarding all of an individual's current prescription drug history. It has been in operation in Manitoba since 1994.

The DPIN system facilitates the benefit/billing process for Pharmacare and also supports the safety of the drug prescribing function by having built-in controls to detect inappropriate drug prescribing and use.

3.2.6 Billings

Pharmacare is intended to be the secondary payer after private drug insurance programs. Pharmacare does not link to private drug insurance programs nor obtain that benefit information for the purposes of reporting claims or benefits. Claimants may be able to receive prescription drug benefits from their insurance program (e.g., Blue Cross) which also enables the claimant to achieve eligibility under Pharmacare quicker, because the private insurance program information is not available to the Province.

Manitoba Health officials advised that a feasible method of addressing this issue has not yet been identified. Ongoing analysis is required to determine the financial impact of how many Manitobans reach their Pharmacare deductible maximum as a result of this, and thereby receive 100% coverage for their prescription costs. This issue will be addressed in our subsequent audit.

Pharmacare reimburses the pharmacy for the cost of the drug dispensed, plus the dispensing fee. *The Prescription Drugs Payment of Benefits Regulation*, established under *The Prescription Drugs Cost Assistance Act*, provides the definition:

> *"cost of specified drug means:*
>
> *a) where a specified drug is purchased in Manitoba, a sum not exceeding*
>
> *1. the price of the specified drug to the pharmacist or holder of the pharmacy license, and*
> *2. a professional fee equal to the amount regularly charged by a pharmacist to people who are responsible for paying the fee without reimbursement, and*
>
> *b) where a specified drug is purchased in a province or territory of Canada other than Manitoba, the cost incurred to a maximum amount that is considered reasonable by the minister."*

Policies regarding prices pharmacies may charge for interchangeable products is identified in subsection 76(1) of *The Pharmaceutical Act* as:

> *"A cost that is not more than the sum of*
>
> - *the cost for the lowest priced interchangeable product prescribed in the Formulary; and*
> - *the maximum additional amount prescribed in the regulations."*

Drug costs for patented drugs are set by the Patent Medicine Price Review Board (a national body). Manufacturers set the price for generic drugs. Pharmacare sets the price at which it will reimburse pharmacies as the maximum allowable price. There is no limit placed on the dispensing fee that a pharmacist may charge Pharmacare.

3.3 PHARMACARE TRENDS

The utilization and cost of Pharmacare has increased significantly over the last number of years from $85.6 million in 1999/00 to $194.4 million in 2004/05. Pharmacare (includes Palliative Care) is only one component of Manitoba Health's drug program which also includes: Family Services; Personal Care Homes; and Acute Care, which is the cost of drugs dispensed to patients in hospitals (**Figure 3**). Total drug costs for all of Manitoba Health's Provincial drug programs increased from $205 million to $327 million from 2000/01 to 2004/05. Pharmacare costs have been approximately 53% to 60% of the total provincial drug program cost over this time period (**Figure 3**).

FIGURE 3

Historical Summary of Provincial Government Drug Expenditures ($millions)

Program	2000/01	2001/02	2002/03	2003/04	2004/05
Pharmacare (includes Palliative Care)	$109	$137	$161	$185	$194
Family Services	29	32	36	40	44
Personal Care Homes (no dispensing fees)	10	12	14	16	15
Acute Care (no dispensing fees)	57	62	66	73	74
	$205	$243	$277	$314	$327

Source: Manitoba Health

Manitoba has experienced higher average cost escalation than most other jurisdictions. However, cost escalation is typical of the experience of all other provinces. Factors typically identified as the primary reasons for the cost increases nationally are:

- Changes in Patent Law (drug patents now extend to 20 years). As a result there is an increasing proportion of patented drugs as compared to generic drugs being used. Patented drugs are typically more expensive;
- Aging population, with accompanying increases in disease, injury and chronic health issues which results in a greater use of all facets the health care system, including the use of prescription drugs;

- Advances in medical care, which has resulted in more diseases that are now treatable with drug therapy, whereas in the past there was no or few drug treatment options for some illnesses;
- Aggressive marketing by drug companies to doctors and patients, promoting the use of newer (and more costly) drugs, which result in changes in physician's treatment and prescribing approaches;
- Lack of aggressive management of the provincial drug Formulary to ensure that the most cost effective drugs (generally generic equivalent drugs) are used as the first line of treatment before allowing the use of newer (patented and generally more expensive) drugs when either may be a treatment option for a given condition;
- Increases in the cost of drugs and dispensing fees being charged; and
- Cost containment practices by private insurance providers which have attempted to shift the cost of drug benefit programs to government programs, where they exist.

Manitoba Health officials advised that they have not analyzed how these factors may have affected the cost of Pharmacare.

The Pharmacare Program Statistical Trends Table (**Figure 4**) was developed by the Office of the Auditor General from information provided by Manitoba Health. Based on the information presented, the following appear to have contributed to the cost increase:

- Number of families receiving benefits has increased from 62,519 in 1999/00 to 87,029 in 2004/05 (40% increase);
- Number of prescriptions processed has increased from 1,819,536 in 1999/00 to 3,084,891 in 2004/05 (70% increase);
- The average drug cost per prescription has increased from $43.95 in 2000/01 to $52.12 in 2004/05 (18.5% increase); and
- The average dispensing fee per prescription has increased from $7.08 in 1999/00 to $10.88 in 2004/05 (54% increase).

FIGURE 4

Pharmacare Program - Statistical Trends - Unaudited
For the Six Year Period Ending March 31, 2005

Program	1999/00	2000/01	2001/02	2002/03	2003/04	2004/05
Number of families receiving benefits(1)	62,519	67,655	78,064	83,098	88,988	87,029
Average family benefit(1)	$1,309	$1,561	$1,669	$1,897	$2,013	$2,185
Average Pharmacare deductible(2)	$709	$718	$721	$718	$745	$804
Number of seniors receiving benefits(1)	50,643	55,138	63,333	65,445	67,144	66,740
Number of Pharmacare prescriptions processed	1,819,536	2,113,862	2,546,214	2,796,732	3,013,772	3,084,891
Average number of prescriptions per family	29.1	31.2	32.6	33.7	33.9	35.5
Average drug cost per prescription	n/a	$43.95	$45.42	$48.46	$51.26	$52.12
Percent increase from prior year	n/a	9.9%	3.3%	6.7%	5.8%	1.7%
Average dispensing fee	$7.08	$7.58	$8.30	$9.04	$10.06	$10.88
Percent increase from prior year	n/a	7.1%	9.5%	8.9%	11.3%	8.2%

(1) Includes Special Drugs Program (SDP) clients (families) who do not pay deductibles.
(2) Includes only non-SDP families who received benefits.

Source: Manitoba Health. Numbers for these years are from published sources (annual reports, annual statistics and internal reports). The numbers for 2004/05 are unpublished and are subject to review. Manitoba Health has stated, *"...the methodologies used to calculate averages for years prior to 2004/05 are unknown and may be inconsistent".*

Pharmacare provides universal coverage for all Manitobans. Therefore any eligible person in Manitoba who applies to Pharmacare may receive benefits once they reach their deductible (**Section 3.1**). In the 2004/05 year Manitoba Health attempted to contain the continuing cost increases in the Pharmacare Program by raising the deductible for the program. It appears that this contributed to slowing the year-to-year rate of growth in the cost of the program from 14.9% in 2003/04 to 5.2% in 2004/05.

4.0 Program Management – Observations and Conclusions

We reached the following overall conclusions in relation to the Program Management audit objective and criteria:

Audit Objective and Criteria	Conclusions
To assess whether Manitoba Health had adequate procedures in place to manage the performance of Pharmacare. In particular, whether: • The objectives of Pharmacare encompassed all key aspects of the program. They should be well defined, measurable and periodically reviewed. • Adequate performance information was available to measure whether a program's mission statement and objectives were being achieved. • Regular evaluation was undertaken of key aspects of program performance and corrective action taken when necessary. • Adequate procedures were in place to ensure compliance with legislation, regulations, and policies and to take corrective action when necessary. This includes having a process in place to identify issues of compliance with key legislation, regulations, and policies of Pharmacare.	Manitoba Health did not have adequate procedures in place to manage the performance of Pharmacare. • Manitoba Health did not have a rigorous planning process in place. Such a process would contribute to the development of comprehensive strategic directions for Pharmacare. • Manitoba Health did not have performance targets or a performance measurement system. As a result, Manitoba Health did not utilize evidence-based data to inform them on how Pharmacare was operating relative to a set of performance targets. • Manitoba Health did not undertake evaluations in relation to a set of performance expectations. Consequently, Manitoba Health did not have documented evidence as to whether: - it was providing the best quality service within available resources; - Pharmacare was operating effectively and efficiently; - legislation, regulations, policies and procedures were working effectively in support of Pharmacare's goals and objectives. • Manitoba Health did not have a system for proactively monitoring compliance with legislation, regulations and policies of Pharmacare. As a result, Manitoba Health did not have a way of knowing whether Pharmacare with over $185.0 million in annual expenditures, was being complied with by pharmacists and physicians. Non-compliance has serious financial implications especially in an era when program costs appear to pose a fundamental threat to the sustainability of Pharmacare.

In reaching the overall conclusions, we examined four key areas that relate to program management:

4.1 Program Direction;
4.2 Performance Information;
4.3 Program Evaluation Practices; and
4.4 Compliance with Legislation.

Detailed audit criteria and observations are presented in the sections that follow.

4.1 PROGRAM DIRECTION

Audit Criteria

The objective of Pharmacare should encompass all key aspects of the program. They should be well defined, measurable and periodically reviewed. Specifically, we looked to determine whether:

- Pharmacare had defined goals and objectives including having a written plan (e.g., a strategic plan) (**Section 4.1.1**);
- Goals/objectives covered all key aspects of Pharmacare (i.e., Pharmacare's core lines of business or it's identified priorities) (**Section 4.1.1**);
- Pharmacare goals, policies and procedures were aligned with relevant legislation, as well as Government and/or Manitoba Health goals; (**Section 4.1.1**)
- Manitoba Health had a clear policy framework for Pharmacare (**Section 4.1.1**);
- Performance targets had been established in relation to Pharmacare's strategic direction (**Section 4.1.2**); and
- There was an established process for periodic review of Pharmacare objectives (**Section 4.1.3**).

4.1.1 Pharmacare's Program Direction Was Weak

OBSERVATIONS

Program Plans

- In August 2004, Manitoba Health prepared a draft Five Year Action Plan that included a section on proposed reforms to Pharmacare in order to sustain the Program.[1] The section on Pharmacare did not go beyond identifying, in general terms, eight areas of activity over the next five years by way of reforms to Pharmacare. The draft plan did not identify goals and objectives for Pharmacare and did not identify performance targets for key aspects of the Program. As well, the draft Plan did not deal with all key aspects of delivering the Pharmacare Program.
- There were three "principles" that Manitoba Health identified as key to sustaining Pharmacare.[2] These were to:
  - Target Pharmacare resources to Manitobans who need them most;
  - Promote cost-effective drug use and prescribing practices; and

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[1] The draft *Five Year Action Plan* has not yet been approved by Manitoba Health executive management and the Minister of Health. As well, the *Five Year Action Plan* did not indicate the five year time frame it was intended to cover.

[2] *Pharmacare A Program for Today and Tomorrow*, p.3.

  - Share the burden of increasing costs among all those who have a stake in prescription drugs.

- These principles have not been translated into a plan of action detailing how they will be realized through the Pharmacare Program.
- As a result, key responsibilities were being performed without the benefit of clear and documented goals and objectives to provide direction and focus to Pharmacare operations.

The Planning Process

- Manitoba Health's planning process did not take active steps to ensure that it was taking every opportunity to align Pharmacare with relevant legislation, Pharmacare's principles, as well as goals of Manitoba Health and Government.
- Manitoba Health management explained that while it did not have a plan for Pharmacare's strategic direction/reforms, it undertook an annual planning exercise in order to develop Pharmacare's proposed budget expenditures for the following year. According to management, this process involved reviewing with the Finance Branch and the Assistant Deputy Minister of Strategic Directions and Provincial Drug Programs, Pharmacare's key issues and proposed initiatives that could be submitted as budget options.
- As such, Manitoba Health's planning process for Pharmacare was geared to the development of the annual budget and budget options rather than the achievement of outcomes. On that basis, we are unable to determine whether Pharmacare's policies and procedures are fully congruent with relevant legislation as well as department and provincial goals.

Policy Framework

- Manitoba Health did not have staff dedicated full-time to Pharmacare policy development and research. Policy work was undertaken by operational staff within Pharmacare in addition to their work in administering this Program.
- Manitoba Health management acknowledged that little work was done in the area of policy development given available resources. As a result, decisions were made about changes to Pharmacare in the absence of a clearly articulated and documented policy framework. By contrast, management noted that the drug program in other jurisdictions such as British Columbia and Ontario have staff assigned to undertake policy work in relation to their drug program.
- Based on our work, we noted that options and recommendations provided to the Minister of Health or to Treasury Board were not generally presented within the context of specific policy objectives or specific health outcomes. Thus the underlying policy aims behind various strategies and activities that were implemented to reform Pharmacare were not clear.

4.1.2 No Performance Targets for Pharmacare for Strategic Direction

OBSERVATIONS

- Pharmacare did not have performance targets in relation to:
    - goals and objectives;
    - the reforms identified in the draft *Five Year Action Plan;*
    - the three key principles identified in *Pharmacare A Program for Today and Tomorrow;* and
    - recommendations presented to the Minister or Treasury Board between 2003 and 2004.
- As well, Manitoba Health had not established performance targets for DPIN even though one of the objectives of DPIN was to facilitate drug/ health outcomes measurement and management. The draft *Five Year Action Plan* identified evidence-based management as one of the principles Manitoba Health supports in order to ensure that *"services provided by the health system are informed by sound research and evaluation related to best outcome and optimal benefit"*.[3]

4.1.3 No Process for Periodic Review of Strategic Direction

OBSERVATIONS

- Manitoba Health's management did not have a process for periodic review of Pharmacare's strategic direction.
- Without an established process for regular review of Pharmacare's strategic direction, opportunities for continuous improvement are more difficult to systematically identify and implement.
- Although a consultant was hired in 2003/04 to undertake a review of Pharmacare, the review was not initiated by Manitoba Health management but by the Minister of Health. The focus of this review was on Pharmacare costs.

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[3] *Five Year Action Plan*, draft August 2004, p.7.

4.2 PERFORMANCE INFORMATION

Audit Criteria

Adequate performance information should be available to measure whether a program's mission statement and objectives are being achieved. This means that there is a performance measurement system in place that enables a program to track its efficiency and effectiveness. More specifically, we examined whether:

- Pharmacare had performance measures and if they were a balanced mix of inputs, outputs and outcome measures. (A mix of measures is desirable because it helps to give a complete picture on performance) (**Section 4.2.1**);
- Performance data enables Manitoba Health to determine if the drugs on the Formulary are achieving intended health outcomes (**Section 4.2.1**); and
- Performance data enables Manitoba Health to determine the extent to which the Pharmacare's operating objectives and outcomes were being achieved (**Section 4.2.1**).

4.2.1 No Performance Measurement System for Pharmacare

OBSERVATIONS

- Manitoba Health did not have a set of performance indicators for measuring how efficiently and effectively Pharmacare was being delivered. However, in its draft Five Year Action Plan Manitoba Health identified the importance of relying on performance information as follows:
  - *"**Evidence-Based:** Services provided by the health system are informed by sound research and evaluation related to best outcome and optimal benefit."*[4]
  - *"**Accountability:** Clear delineation of roles and responsibilities throughout the system will be maintained. This will include mechanisms and processes for establishing performance expectations, measuring progress and evaluating results."*[5]
- One of the objectives of DPIN is *"to facilitate drug/health outcomes measurement and management"*.[6]
  - Manitoba Health prepared a proposal for a Drug Management Agency with a stated aim of maximizing health outcomes.

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[4] A *Five Year Action Plan*, draft August 4, 2004, p.7.

[5] A *Five Year Action Plan*, draft August 4, 2004, p.7.

[6] *Pharmacare Overview*, p.2.

- Treasury Board required departments to submit with their proposed budget a *Priorities and Strategies Overview* that includes outcome measures. The form on *Priorities and Strategies Overview* indicated that:

> *"This section is to focus on the results of department actions against desired outcomes. They are client focused and related to the purpose of the program, not its outputs. For example, an outcome for an addictions counseling program would be that clients control their addictions. The outputs of the program would be the number of counseling sessions held or the number of people assisted.*
>
> *If the department is now collecting data or if independent data related to the program area exists, please provide a summary (historical or otherwise) and the source, where applicable, and a brief assessment of how actual results compared to desired outcomes."*[7]

- We noted that Manitoba Health's 2003/04 *Priorities and Strategies Overview* did not contain any performance measures for Pharmacare or for any other programs/initiatives of Manitoba Health.
- Management advised that cost effectiveness was the performance standard for Pharmacare. Costs were assessed in relation to their therapeutic aspect and financial impact. Manitoba Health management explained that they examine both aspects, and in those cases where a drug will not be cost neutral, Treasury Board approval is required.
- There were other key aspects of Pharmacare for which performance information was not collected, such as:
    - Health outcomes of prescription drugs;
    - Achievement of performance expectations related to the operation of Pharmacare; and
    - The achievement of specific targets to be established in relation to Pharmacare concerns such as drug costs.
- Thus, given the lack of performance data, Manitoba Health decisions on the allocation of resources and changes in policy and procedure were being made without the benefit of performance data to substantiate such decisions. As well, there was a lack of evidence-based information on whether resources were being utilized appropriately with sufficient regard to efficiency and effectiveness. For instance, documentation prepared, substantiated the recommendations by citing various benefits attributed to prescription drugs (i.e., ensures that seniors have access to effective new medicines, can reduce hospitalization rates and nursing home admissions; can help seniors live independently longer, can save health care resources). However as Manitoba Health management indicated, these are theoretical, purported benefits. They were not based on performance data specific to Pharmacare.

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[7] *2003/04 Preliminary Estimates Forms*

4.3 PROGRAM EVALUATION PRACTICES

Audit Criteria

A program should have adequate standards to evaluate its performance. Part of this expectation is that regular evaluation would be undertaken of key aspects of a program's performance and corrective action taken when necessary. More specifically, we looked to find whether:

- Manitoba Health had an established and documented process/ procedure for the collection of Pharmacare performance data which included: a schedule of the frequency of data collection; who was responsible for data collection; data quality control; who generated performance reports and who received such reports (**Section 4.3.1**);
- Manitoba Health had an evaluation framework which identified the criteria that guided the selection of which aspects of Pharmacare to evaluate, frequency of evaluations, budget requirements for evaluations, data sources, and so forth (**Section 4.3.2**);
- Evaluations which may have been conducted included: the scope, approach and sampling methodology; the findings; and the required action to address issues that were identified (**Section 4.3.2**); and
- There was a strategy/plan for implementing changes as necessary based on evaluations conducted and when corrective action was not taken, there was documentation as to the rationale for not proceeding with a particular recommendation or proposal (**Section 4.3.3**).

4.3.1 Need for Well Defined Protocol for Data Collection for Pharmacare

OBSERVATIONS

- Manitoba Health management noted that since drug costs are a concern, there was on-going monitoring of drug costs and the following reports were generated:
  - Budget Impact Analysis of new drugs;
  - Pharmacare Weekly Drug Payments; and
  - Six-month spreadsheet on Drugs Prescribed by type of drug, a quarterly projection analysis that includes changes in number of prescriptions and change in dispensing fees.
- In addition to monitoring drug costs, Manitoba Health indicated that pharmacists on staff monitored the information provided by industry on the therapeutic benefits of various drugs. They did this through a variety of ways:

  - by reviewing the literature;
  - determining who industry consulted with to arrive at their information;
  - considering the recommendations from the *Common Drug Review* (established in September 2003 by federal/provincial/territorial Health ministers to provide listing recommendations for new drugs to governments);
  - comparing industry's proposed pricing with pricing of drugs already on the Formulary; and
  - consultations with the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) established in March 2004 by agreement from federal/provincial/territorial ministers to provide research information on best practices in drug prescribing and utilization.

- Manitoba Health had information that compared the scope of drug programs in other Canadian jurisdictions. Manitoba Health advised that this information was updated two or three times a year. Management also advised that they monitored trends in jurisdictions outside Canada.

- While monitoring provided Manitoba Health with some Pharmacare information, there was a lack of a systematic approach to performance data collection. Performance information could include:
  - identifying which Pharmacare goals and objectives are to be measured;
  - the frequency of measurement;
  - who will be responsible for data collection;
  - data sources;
  - procedures to be followed to ensure data quality control;
  - who will prepare performance reports;
  - the frequency of generating such reports; and
  - who is to receive these reports.

4.3.2 Need for an Internal Evaluation Framework for Pharmacare

OBSERVATIONS

- Manitoba Health did not have an evaluation framework, and did not conduct regular, periodic evaluations. However, in 2002/03 an evaluation was undertaken by a consultant at the request of the former Minister of Health that focused on Pharmacare costs. The consultant reported directly to the Minister of Health on that evaluation. Although they were interviewed by the consultant, Manitoba Health was not involved in giving direction to this evaluation.

- Manitoba Health did not have documented evidence as to whether Pharmacare was being administered as well as it could be within the context of available resources. Likewise, without evaluation information, it was difficult to implement continuous improvement in a meaningful way.

4.3.3 Consultant's Proposals Being Implemented

OBSERVATIONS

- The consultant who undertook the Pharmacare evaluation initiated by the Minister of Health identified several proposals that would attempt to control Pharmacare program costs in the future. From discussions with Manitoba Health, they have either implemented (e.g., amending the deductibles) or were in the process of determining the feasibility of implementing the consultant's proposals (e.g., the drug management agency).
- While the consultant's proposals were being acted on or are under further exploration, management did not have a documented strategy that articulated a plan for rolling out the proposals put forward by the consultant.

4.4 COMPLIANCE WITH LEGISLATION

Audit Criteria

Adequate procedures should be in place to ensure compliance with legislation, regulations, and policies and to take corrective action when necessary. This includes having a process in place to identify issues of compliance with key legislation, regulations, and policies of Pharmacare including:

- Making false or misleading information; (section 4 of *The Prescription Drug Cost Assistance Act*);
- Issuing false prescriptions; (section 6 of *The Prescription Drug Cost Assistance Act*);
- False dispensing of drugs; (section 7 of *The Prescription Drug Cost Assistance Act*);
- Issuing false receipts for drugs; (section 8 of *The Prescription Drug Cost Assistance Act*);
- Proper application of substitution of interchangeable products; (subsection 76(1) of *The Pharmaceutical Act*);
- Accurate billing by pharmacists; and
- Accurate application of Parts 1, 2, and 3 of the Formulary by physicians.

4.4.1 Compliance Process Was Reactive

OBSERVATIONS

- Manitoba Health did not monitor compliance with the legislation, regulations and policies of Pharmacare. Manitoba Health did not have an annual plan of the Pharmacare issues to monitor, and the Audit and Investigations Unit within Manitoba Health responded to requests for compliance audits as they arose. Compliance issues pertaining to Pharmacare came to them through several sources including: the Director of Pharmacare, the Pharmaceutical Association, and the Tip Hot Line of Manitoba Health.
- The Audit and Investigations Unit within Manitoba Health noted that they had developed a computerized database and program that will enable them to correlate different data together to form an overview of activities within Pharmacare. This information will enable them to identify areas requiring audit or investigation. They advised that they recognize that Pharmacare is receiving insufficient compliance attention and that they were in a reactive mode responding to specific compliance requests as opposed to annually planning and executing compliance reviews of different aspects of Pharmacare.
- In 1975, there were three auditors and one support person, within Manitoba Health, to undertake audits pertaining to physicians and fraudulent health cards. Since then, the mandate of the three auditors has expanded to include, Pharmacare, chiropractors, special requests from the Assistant Deputy Minister/Deputy Minister, and monitoring health labour contracts.
- The Audit and Investigations Unit within Manitoba Health noted that several jurisdictions have auditors who audit the drug program on a full-time basis. These included: British Columbia with six such auditors, Nova Scotia with two, and Newfoundland with one full-time auditor and one part-time auditor for the drug program.

5.0 Drug Selection and Cost – Observations and Conclusions

We reached the following overall conclusions on the drug selection and cost audit objective and audit criteria:

Audit Objective and Criteria	**Conclusions**
To assess whether Manitoba Health had adequate procedures in place to ensure resources were managed with due care for cost effectiveness in relation to Pharmacare In particular, whether: • Drugs were properly assessed to ensure they were cost effective and drugs met pharmaceutical effectiveness criteria before being added to Pharmacare. • Drugs listed, on the Formulary, were regularly evaluated to determine whether they should continue to be listed, covered under special exception conditions, or removed from the listing. • Drugs under assessment were fast tracked for faster inclusion to or deletion from the list. • There were policies and processes in place to ensure that drugs listed on the Formulary and fees for dispensing those drugs were acquired at the lowest possible cost. • Manitoba Health analyzed commercial marketing practices to determine if they have an impact on the Pharmacare program and strategies. • Prices of drugs were followed-up and analyzed and, if necessary, audited.	Although Manitoba Health had processes in place to assess drugs for selection and then listing on its Formulary, it did not have adequate processes in place to ensure Pharmacare was managed with due care for cost effectiveness. • Drugs listed on the Formulary were assessed for proposed pharmaceutical and cost effectiveness by an independent advisory committee prior to their placement on the Formulary. There was no evidence to confirm whether the proposed cost effectiveness of those drugs was being achieved. • There was no approved documentation of the drug review process. Various informal documents described the assessment and selection of drugs for listing, thereby creating a risk that expected protocols may not have been followed. • Drugs listed on the Formulary were not regularly evaluated for effectiveness once they had been added to the listing. Drugs maintained on the listing may not be still providing the most cost effective and therapeutic benefits, based upon current pricing, clinical knowledge and practice. • There was no process for fast tracking cost effective drugs to be added to the Formulary faster or to remove drugs that should be avoided sooner. As a consequence of not having a fast tracking process, some potential cost savings may not have been realized. • Although policies and procedures were in place over such areas as the use of generic drugs and lowest cost pricing of drugs in the Formulary, additional strategies and procedures, such as the use of Reference Based Pricing or bulk purchasing, could be implemented to provide significant savings. • The uncontrolled cost of dispensing fees has added substantially to the increasing costs of Pharmacare. Manitoba Health estimated that dispensing fees account for 17% of Pharmacare costs, which for the 2004/05 fiscal year would amount to over $33 million. • Manitoba Health recognized that the impact of drug manufacturers' commercial marketing practices may have increased Pharmacare costs. There has been inadequate monitoring of such commercial marketing practices to determine their affect on Pharmacare costs. • DPIN controls were in place so that drug prices reimbursed to pharmacies were in line with Pharmacare drug pricing policies. However, there was no periodic analysis of those controls and no corrective action taken to ensure input and processing controls were effective.

In reaching the overall conclusions, we examined six key areas that relate to drug selection for listing on the Formulary and the cost of those drugs to Pharmacare:

5.1 Drug Assessment and Selection for Initial Listing;
5.2 Periodic Review of Drugs on the Formulary;
5.3 Fast Tracking Changes to the Formulary;
5.4 Lowest Cost Strategy;
5.5 Impact of Commercial Marketing Practices; and
5.6 Drug Price Controls and Auditing.

Detailed audit criteria and observations are presented in the related sections.

5.1 DRUG ASSESSMENT AND SELECTION FOR INITIAL LISTING

Audit Criteria

Drugs should be properly assessed to ensure they are cost effective before being added to the Formulary. Proper assessment includes ensuring the drugs meet pharmaceutical effectiveness criteria. Specifically, we reviewed whether:

- There were criteria in place for the review of whether to add, restrict, or remove drugs from the list of drugs eligible for Pharmacare coverage that considers both cost effectiveness and the pharmaceutical effectiveness of the drugs (**Section 5.1.1**); and
- There was a function with defined roles and responsibilities for carrying out drug assessments which makes decisions regarding which drugs to add, maintain, remove, or replace (**Section 5.1.2**).

5.1.1 A Process Was In Place To Review Drugs Prior To Adding Them To Or Deleting Them From The Formulary - No Analysis Was Performed On Actual Costs Savings Of The Drugs Added

OBSERVATIONS

- New drugs are constantly being introduced to the market by drug manufacturers. One of the key challenges for any drug program is determining which drugs to include in a provincial jurisdiction's drug benefit program and their approved drug listing (Formulary). Each provincial jurisdiction has autonomy in this complex listing process.
- Manitoba Health had several documents that detailed the processes that were in place to review drugs prior to placing them on the Formulary, as follows:
  - The Manitoba Health website outlined a process titled, *Manitoba Drug Standards and Therapeutics Committee (MDSTC) Submission Requirements*, that drug manufacturers need to follow in order to have their drug considered for listing in Manitoba. This process was last updated in September 2003.

  - Manitoba Health identified the internal process for listing drugs on the Formulary as being outlined in a few documents:
    - The main document used by Manitoba Health to assess new drugs for inclusion and current drugs for continued inclusion or deletion from the Formulary, was referred to as *The Formulary Policy and Procedures* document. We were advised that it was developed around 1992.
    - Manitoba Health also identified a second document called *The Formulary Process* that outlined the process.

- None of these documented procedures appeared to have been formally approved, by Manitoba Health, as the unequivocal guide for the Formulary review although the documents were not fundamentally different.

- The processes above identified the criteria for a review of drugs for their cost effectiveness and pharmaceutical effectiveness. That process for review occurs every three to four months and was followed through the following steps:
  - the manufacturers' submission;
  - Manitoba Health analysis;
  - MDSTC review; and
  - recommendation to the Minister.

- As part of the initial evaluation process, an economic assessment of each drug was performed prior to its being placed on the Formulary and included a projection of annual cost savings. Some of that economic assessment was provided by the drug companies in their submission for their drugs to be added to the Formulary. However, no analysis was performed on the actual costs savings of the drugs after being added to the Formulary as compared to the proposed cost savings.

- Once drugs have received approval, from the Minister of Health, for addition to or deletion from the Formulary, Manitoba Health was responsible for updating the Formulary. The Formulary was updated, via a *Manitoba Drug Benefits and Interchangeability Formulary Amendments Bulletin* (Bulletin) approximately every three to four months. These Bulletins were posted on the Manitoba Health website and sent to pharmacies and physicians.

- Our comparisons to other jurisdictions found other provinces have a process of drug evaluation similar to Manitoba's (**Section 3.2**).

5.1.2 Expert Advisory Committee Reviewed Drugs and Recommended Changes To The Formulary - New National Drug Review Committee's Process Was Not Utilized To Improve Efficiency Until December 2004

OBSERVATIONS

- As noted in **Section 3.2**, MDSTC is an independent committee, made up of professionals nominated by professional bodies and appointed by the Minister of Health to review drugs prior to adding them to the Formulary. MDSTC also reviewed recommended changes to, and deletions from, the Formulary.
- The Terms of Reference, dated September, 1998, documented the Roles and Responsibilities of MDSTC, and defined the membership as:
  - *"The Committee shall be comprised of at least six (6) individuals with expertise in the areas defined by the objectives."*
- The Terms of Reference also identified MDSTC's objectives as follows:
  - To assist Manitoba Health in determining which drugs will be provided to Manitobans by government programs;
  - To assist Manitoba Health in determining which drugs and drug products are interchangeable;
  - To assist Manitoba Health in assuring that government drug benefits are rational and cost effective; and
  - To assist Manitoba Health in addressing other drug utilization issues.
- MDSTC made recommendations on drug interchangeability and on the therapeutic and economic value of drugs based on their review of the drug manufacturers' submissions for inclusion on the Formulary. Based on MDSTC's recommendations, the Minister of Health gave the final approval for the drugs to be eligible for Pharmacare benefits and to be added to the Formulary.
- In addition to Manitoba's review process, in 2002/03 Manitoba participated in the federal/provincial/territorial development of the Common Drug Review (CDR) process. This resulted in the development of the Canadian Expert Drug Advisory Committee (CEDAC) to improve the overall efficiency and effectiveness of drug reviews. CEDAC's eleven members were appointed by the Conference of Deputy Ministers of Health and selected on the basis of their expertise in the evaluation of therapeutic value and cost-effectiveness of drug products.
- As of September 2003, the CDR was given responsibility to perform a review of new chemical entities and new drugs. In April 2004, the CEDAC had its first meeting to make listing recommendations including conditions for coverage. Health departments can review that list and decide whether to accept the recommendations as they affect their Formularies.

- It is expected that the CDR will enhance some of the activities of the jurisdictional committees' work. There was no reflection of the impact of the CDR during our review of Pharmacare. Manitoba Health continued with its review process and implemented the CDR in December 2004.

5.2 PERIODIC REVIEW OF DRUGS ON THE FORMULARY

Audit Criteria

Drugs listed on the Formulary should be regularly evaluated to determine whether they should continue to be listed, covered under special exception conditions, or removed from the listing.

Specifically, we looked to find whether:

- **There were guidelines for a periodic review of listed drugs to determine their continuing eligibility on the Formulary, at specified intervals (Section 5.2.1);**
- **There was evidence of periodic review being followed as established by Manitoba Health (Section 5.2.1); and**
- **Corrective action was taken based on the findings and recommendations (Section 5.2.1).**

5.2.1 Periodic Review Of The Formulary Was Not Being Undertaken As Required

OBSERVATIONS

- A Formulary review process was identified in the MDSTC Terms of Reference dated September 1998. Those terms of reference were reaffirmed in a communication from the Minister of Health, dated October 2002 which stated one of the functions of MDSTC was:
  - *"To periodically reassess drugs and drug products to determine the appropriateness of their continued eligibility as benefits."*
- During the period of our audit, June 2004 to June 2005, there was no evidence of a periodic reassessment. However, there was evidence of a class review of drugs used to treat Diabetes.
- Manitoba Health stated that in 2002 a review was commenced on Part 2 Drug Identification Number (DINs), although it was not completed. Part 2 of the Formulary includes drug products that are eligible for Pharmacare benefits only when prescribed for certain terms and conditions.
- Manitoba Health officials advised that they were planning to begin a review process with MDSTC in 2005. That process had not begun at the time we concluded our audit field work.

5.3 FAST TRACKING CHANGES TO THE FORMULARY

Audit Criteria

Drugs under assessment that have the potential for cost savings or increased health benefits, or that should be avoided because of high cost or health risk, should be fast tracked for faster inclusion to or deletion from the list.

There should be an adequate process which includes:

- Timely decision making;
- A faster process than the normal review;
- Consideration of therapeutic aspects;
- Identification of specific costs savings by using that drug;
- Identification of drugs that should be avoided; and
- Evidence of the process being used (**Section 5.3.1**).

5.3.1 No Process For Fast Tracking The Addition Or Removal Of Drug From The Formulary

OBSERVATIONS

- Manitoba Health had no fast tracking process to identify and add lower cost drugs that would have provided proposed cost savings if utilized, nor for quickly removing drugs that should be avoided due to higher costs or therapeutic reasons.
- The normal drug evaluation process discussed in **Section 5.1.1** took three to four months to complete.
- Health Canada notified Provincial Health Departments and pharmacists of drugs which they deemed should be removed from the market for health risk. Upon receipt of the Health Canada Warnings, Manitoba Health appropriately and immediately removed those drugs from the Formulary without going through the standard MDSTC review process.

5.4 LOWEST COST STRATEGY

Audit Criteria

There should be policies and processes in place to ensure that drugs listed on the Formulary and dispensing fees for dispensing drugs are acquired at the lowest possible cost.

Specifically, we looked to find whether:

- **There were policies and procedures in place to ensure drugs were acquired at the lowest possible cost. This could have included the use of competitive processes, generic drugs, and volume discounts (Section 5.4.1); and**
- **There were policies and procedures in place to establish and control dispensing fees (Section 5.4.2).**

5.4.1 Opportunity To Improve Drug Costing And Enhance Financial Sustainability of Pharmacare

OBSERVATIONS

Drug Cost Policies and Procedures

- *The Prescription Drugs Cost Assistance Act, Prescription Drugs Payment of Benefits Regulation* was the legislation which established processes to ensure drugs listed on the Formulary were acquired at the lowest possible price.
- Policies regarding prices that pharmacies may charge for interchangeable drug products are identified in subsection 76(1) of *The Pharmaceutical Act.*
- Manitoba Health set the maximum allowable price that was reimbursed for brand name drugs. The price was based on the drug manufacturer's suggested price and the maximum price of that drug in the Formulary. Where there were chemically equivalent, interchangeable, lower priced generic equivalents available and listed in the Formulary, the price would be set to the price of the lower priced generic equivalent. For reimbursement purposes, Manitoba Health does not normally compare chemically different drugs with the same therapeutic treatment in order to set the price. If they did, that would be considered to be Reference Based Pricing.
- A price was established by Pharmacare as the price to be paid to pharmacies, through DPIN, for eligible drugs dispensed to Pharmacare recipients. Drug prices within the DPIN system included a mark-up of up to 10% on the manufacturers' price of some drugs. The markup was added to allow room for anticipated future price increases and/or variances in prices of different wholesalers. The markup cuts down on

day to day administration that would be incurred by Manitoba Health in changing the prices every time the manufacturer makes a price change.

- To keep pricing current, prices for non-interchangeable drugs eligible for Pharmacare benefits could be changed by way of wholesalers' price changes. These price changes were often presented by pharmacists via submitted Pharmacare claims that had drug prices different than the price allowed in DPIN. Manitoba Health followed up with the wholesalers to confirm the price and then the drug prices were changed in DPIN if necessary. Only authorized staff could make the price changes in DPIN.
- As noted in **Section 5.6.2**, Manitoba Health did not follow up on manufacturers' price changes to assess how they affected the original MDSTC recommendations and approved pricing.
- We verified prices noted on a sample of the drug approvals (MDSTC Meeting minutes) to the prices applied in DPIN and found no discrepancies.
- Although economic assessments of drugs were performed prior to being placed on the Formulary and annual proposed cost savings were projected, some of that information was provided by the drug companies in their submissions to Pharmacare. Manitoba Health did not analyze actual cost savings of the drugs as compared to the proposed cost savings.

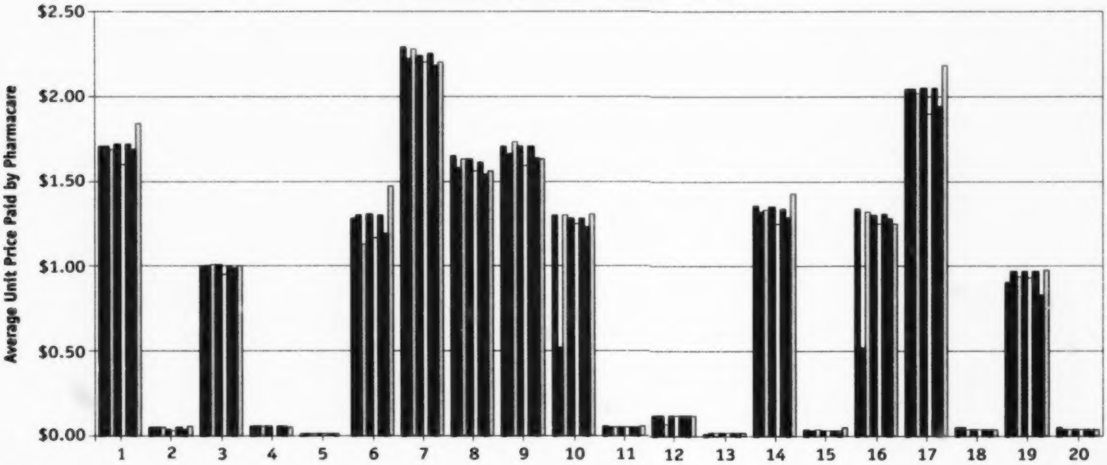
Drug Cost Comparisons Across Canada

- Manitoba Health has indicated that Manitoba was one of the first provinces to introduce a "Lowest Cost Alternative Strategy" in 1974.
- The following are some Cost Management Strategies identified in a review of other large drug benefit programs in Canada that could be used for setting a brand drug price on the Formulary.
  - **Large Volume Purchasing** - A common procurement strategy whereby unit costs drop as purchase volume allows.
  - **Lowest Cost Alternative** – The least expensive of several drugs that are all chemically identical and therapeutically equivalent. These drugs are thus interchangeable. Pharmacists are to follow provincial and territorial pharmacy legislation and policies to identify interchangeable products and to select the lowest priced brand (similar to the system in use by Manitoba Pharmacare).
  - **Reference Based Costing** – The process whereby, in a class of drugs of similar therapeutic efficacy (may or may not be chemically equivalent but are therapeutically equivalent) normally only the cost of the least expensive drug is reimbursed. If more expensive drugs in the class are used and not approved through a medical exceptions process, the reimbursement limit is the cost of the least expensive drug, with the patient paying the difference (also known as Reference Based Pricing).

- *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada* prepared by the Patented Medicine Prices Review Board, November 2002, reported the cost benefits of generic drugs as noted in the following:
  - On average, the prices of the top selling generic drugs in Canada were 35.5% lower than the prices of the equivalent brand name drugs in 2000. The generic-to-brand name price ratio was 64.5%.
  - The spread between generic and equivalent brand name drug prices varied depending on the number of generic versions of the drug available. On average, the spread increased from about 25% when there were one to three generic versions on the market to 45% when there were four or five generic sources. As a consequence, there is inconsistency in the pricing of similar generic products across jurisdictions in Canada. Some jurisdictions also include Over the Counter Drugs in a Reference Drug Program as part of their Pharmacare program.
  - The reimbursed prices for multiple source drugs tend to be similar across Canada.
- To further assess low cost pricing policies, we used data that was available in all jurisdictions for the 2002/03 year data, and compared the cost of the 20 top brand name, patented drugs sold across Canada. The results of that analysis are illustrated in **Figure 5**.

FIGURE 5

Drug Price Comparison Across Canada
Top 20 Patented Drugs Sold in Canada - 2002/03



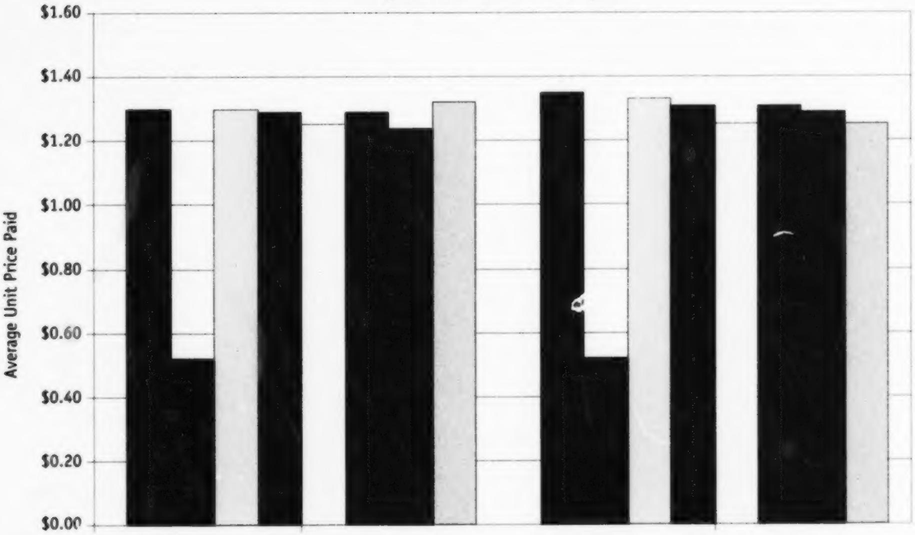
Jurisdictions *Legend (left to right):*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
■ Manitoba	$1.71	$0.05	$1.00	$0.06	$0.01	$1.28	$2.29	$1.65	$1.71	$1.30	$0.06	$0.12	$0.01	$1.36	$0.04	$1.34	$2.04	$0.05	$0.91	$0.05
■ A	$1.71	$0.05	$1.00	$0.06	$0.01	$1.30	$2.22	$1.58	$1.66	$0.52	$0.05	$0.12	$0.02	$1.32	$0.03	$0.52	$2.04	$0.05	$0.97	$0.04
□ B	$1.69	$0.05	$1.01	$0.06	$0.01	$1.13	$2.28	$1.63	$1.73	$1.30	$0.05	$0.07	$0.02	$1.33	$0.04	$1.32	$2.02	$0.04	$0.94	$0.04
■ C	$1.72	$0.04	$1.01	$0.06	$0.01	$1.31	$2.24	$1.63	$1.71	$1.28	$0.05	$0.12	$0.02	$1.35	$0.03	$1.30	$2.05	$0.04	$0.97	$0.04
□ D	$1.60	$0.03	$0.95	$0.00	$0.01	$1.17	$2.20	$1.56	$1.59	$1.25	$0.05	$0.12	$0.02	$1.25	$0.03	$1.25	$1.90	$0.04	$0.93	$0.04
■ E	$1.72	$0.05	$1.00	$0.06	$0.01	$1.30	$2.25	$1.61	$1.71	$1.28	$0.05	$0.12	$0.02	$1.34	$0.03	$1.31	$2.05	$0.04	$0.97	$0.04
■ F	$1.69	$0.04	$0.99	$0.06	$0.01	$1.19	$2.18	$1.54	$1.64	$1.23	$0.05	$0.12	$0.02	$1.29	$0.03	$1.28	$1.94	$0.04	$0.83	$0.04
□ G	$1.84	$0.06	$1.00	$0.05	$0.00	$1.47	$2.20	$1.56	$1.63	$1.31	$0.06	$0.12	$0.02	$1.43	$0.05	$1.25	$2.18	$0.04	$0.98	$0.04

Source: Canadian Council of Legislative Auditors - Health Study Group

- **Figure 5** indicates that there may be a range of prices for different drugs. For example, for drug #2 the average cost was $0.03 to $0.06 per unit vs. drug #1 where the average cost was $1.60 to $1.84 per unit. However, the average unit price paid for each of those individual 20 drugs was similar in all eight jurisdictions. Our analysis aligns with the Patented Medicine Study which reported that reimbursed prices for multiple source drugs tends to be similar across Canada.
- In Manitoba, the 20 drugs compared in **Figure 5** accounted for approximately 461,000 prescriptions (or 16% of prescriptions claimed under Pharmacare) in the 2002/03 year, costing Pharmacare $23.3 million. The cost of those 20 drugs represented 14% of the total spent on drugs under Pharmacare in 2002/03.
- Two of the 20 drugs (drug #10 and drug #16) appeared to have a lower price in one of the jurisdictions. An analysis of those two drug prices is presented in **Figure 6**. That jurisdiction advised that the lower drug prices were as a result of Reference Based Pricing applied on those two drugs.

FIGURE 6

**Outliers in Drug Price Comparison
Drugs #10 and #16 - 2002/03**



Jurisdictions *Legend (left to right):*	Drug #10	Drug #16
■ Manitoba	$1.30	$1.35
■ A	$0.52	$0.52
□ B	$1.30	$1.33
■ C	$1.29	$1.31
□ D	$1.25	$1.25
■ E	$1.29	$1.31
■ F	$1.24	$1.29
▨ G	$1.32	$1.25

Source: Canadian Council of Legislative Auditors - Health Study Group

- Manitoba currently sets a maximum allowable price to the lowest cost alternative price for drugs in the Formulary which allows only drugs that are chemically equivalent to be interchangeable. Reference Based Pricing includes drugs which may not be chemically equivalent but have similar therapeutic efficacy (similar treatment). Manitoba Health could potentially have realized additional cost savings of over $2.6 million in 2002/03 on those two drugs alone if Reference Based Pricing were used. (Based on 1,511,683 units of drug #10 at a cost saving of $0.78 and 1,807,399 units of drug #16 at a cost savings of $0.82.)

- In an *Impact Statement on Therapeutic Category Pricing Option* prepared by the Department of Health, October 2002, it was noted that:

    - *"The estimated cost reductions of the proposed Manitoba Pharmacare Program Therapeutic Category Pricing Model using Pharmacare Program 2001/02 utilization data for the five therapeutic drug categories included in the British Columbia program is $5,762,016.*

    - *Therapeutic Pricing options also known as Therapeutic reference based pricing systems involves clustering of comparable drugs that contain different chemical structures that are equally effective in treating a particular condition.*

    - *In therapeutic reference based pricing systems, the reference factor is price not volume, quality of prescribing, health economic considerations and/or outcomes of medical results.*

    - *Two jurisdictions in Canada have implemented versions of therapeutic reference pricing systems, British Columbia and Nova Scotia. Variations of reference based pricing systems are also found in Europe, the United States, New Zealand, Australia, Germany, and other countries."*

Pricing Strategy Review

- We compared procedures on conducting price reviews across eight jurisdictions in Canada, and concluded that procedures for conducting price reviews were similar across Canada.

- Manitoba Health had taken steps to analyze best practices in pricing and attempted to address pricing strategy issues by participating in, and reviewing, numerous studies on prices of medicines performed by the Patented Medicine Prices Review Board and other bodies. Results of those studies were used in internal discussions on pricing strategy.

- Manitoba Health prepared a *Pricing Strategy* paper, dated December 20, 2004 to address mark-ups and price changes. At the conclusion of our audit, there was no evidence that this strategy had been put forward to Cabinet.

Tendering for Bulk Purchase of Generic Drugs

- In Fall 2003, Manitoba Health entered into discussion with officials from the Saskatchewan Health drug plan to initiate formal discussion for joint tendering of generic drugs. Saskatchewan Health officials advised

Manitoba Health that they would not be partnering on the bulk purchase tendering of drugs due to a concern that collaboration with Manitoba might lead to shortages of product for Saskatchewan residents.

- An accepted tender requires the manufacturer to guarantee delivery of a drug through approved distribution channels. The successful company would agree to sell, distribute, or wholesale its generic drug to Manitoba companies at an agreed upon factory price.
- Manitoba Health noted that generic manufacturers focus their marketing efforts on pharmacists and distributors who make the decisions about which generic drugs to dispense. The impact of marketing efforts to pharmacists likely reduces the potential financial benefit to the Province of rebates or reimbursements which are reported to average 40% of product cost. Bulk purchasing would shift the financial savings benefit from drug stores to the Province through lower prices.
- In March 2004, Manitoba Health issued a Request for Quotations (RFQ) to pre-qualify companies in a proposed future competition process whereby only one alternative generic drug in each of 38 certain Interchangeable Drug Groups would be eligible for reimbursement under Pharmacare. Twelve companies indicated an interest in the RFQ.
- Two months later in May 2004, the President of an organization representing generic pharmaceutical companies submitted a letter to the Government in which the organization identified some of its concerns with respect to a potential competitive process for generic drugs. He indicated that he wished to caution government about the pursuit of a generic drug tendering system and that overall savings to a drug plan must be kept in perspective. That perspective included, among others, the incentive to produce new drugs, reduction of competition, production and supply concerns, and that the tendering process would be viewed as a disincentive for future investments in the province.
- In early June 2004, the Assistant Deputy Minister of Provincial Health Programs responded to the President of that organization and noted a meeting with the Department of Health would not be appropriate until after the response deadline for the RFQ has passed.
- Two manufacturer's representatives advised the province that they would not be submitting a response to the RFQ expressing concerns and opposition to the tendering for generic drugs.
- A single response was received from one pharmaceutical manufacturing and distribution company which currently supplies the Winnipeg and Brandon hospitals. Manitoba Health's legal counsel advised that the RFQ should be deleted or aborted and to advise the one respondent. That respondent was to be contacted to determine if a sole source contract for a select group of generic products was of interest.
- There did not appear to be any further analysis for tendering for bulk purchasing. The last Manitoba Health internal correspondence dated

October 2004 on tendering stated:

> *"The lack of response from manufacturers signals a lack of support for a future tendering process. It was recommended that the RFQ process be cancelled and not to proceed to a solicitation process inviting the quotation of prices."*

- Saskatchewan is the only jurisdiction that uses bulk purchasing for pharmacies to provide lower drug prices. Tendering for bulk purchasing of drugs is common in hospitals across Canada. Bulk tendering is used by the Winnipeg Regional Health Authority to purchase drugs for hospitals.
- Manitoba Health officials advised that there are limitations for volume purchasing in all jurisdictions due to external factors, such as small Canadian market next to the largest unregulated market (USA), resistance by vendors, Patented Medicine Review Board price guidelines, and increased supply chain costs.

5.4.2 No Controls Over Cost Of Dispensing Fees

OBSERVATIONS

- In addition to the costs of the drugs themselves, dispensing fees and compounding fees were charged by pharmacies and reimbursed by Pharmacare.
    - The dispensing fee is intended to cover the costs of salary and benefits of pharmacist, technicians and other pharmacy dispensing staff, containers, labels, computer systems, license fees and memberships, liability insurance and other costs of maintaining a pharmacy, beyond the cost of the drugs themselves.
    - Compounding fees may be charged for preparing a compound medication where it is not commercially available, and may require the processing of raw material in a sterile environment to make a drug.

Dispensing Fee Controls

- Prior to 1994, Pharmacare had a regulated limit or cap on dispensing fees. In 1994, the cap was lifted and since then the dispensing fees have been determined by the market place. Under *The Prescription Drug Cost Assistance Act*, Manitoba pharmacists have been permitted to charge Pharmacare a fee that is equal to the amount regularly charged to people who pay their own fees without Pharmacare reimbursement.
- In a review of individual dispensing fees paid to pharmacies, we found they ranged from under $6 at a large box retailer to over $12 at certain retail pharmacy chains, both in Winnipeg and in rural areas. Manitoba Health advised that many people are not aware of the variations in dispensing fees. As a result of there being no limit on dispensing fees, there is a risk that more may have been paid out through Pharmacare than necessary.

- Manitoba Health's documentation of a strategy to address dispensing fees, identified a scheduled implementation of a cap on dispensing fees for January 1, 2005. In that documentation, it was estimated that dispensing fees account for 17% of Pharmacare costs. For 2003/04 that would have amounted to $31.4 million (over $33 million for 2004/05). At the conclusion of the field work of our audit, that cap had not been implemented.
- The Manitoba Society of Pharmacists (MSP), a not-for-profit, voluntary organization whose purpose is to advance the economic and professional interests of its members, had made arrangements with Manitoba Family Services and Housing for the delivery of pharmaceutical and drug services to Employment and Income Assistance (EIA) participants for a $6.95 cap on dispensing fees. MSP also negotiated a $9.53 cap on dispensing fees for First Nations and Inuit Health Branch drug benefits which are paid for under federal government programs.
- There was no agreement with the MSP regarding controlling dispensing fees for Pharmacare recipients.

Analysis of Dispensing Fees

- We compared the average dispensing fees paid by provincial drug programs for those 20 drugs from **Figure 5** for the year 2002/03 as shown in **Figure 7**.

FIGURE 7

Average Dispensing Fees Paid On Top 20 Patented Drugs Sold 2002/03

Jurisdiction	Lowest Average Fee for one drug(1)	Cap or Limit	Highest Average Fee for one drug(2)	Average for All 20 Drugs(3)
Manitoba	$7.47	N/A	$14.00	$9.10
A	$6.38	Maximum $8.25	$7.40	$6.76
B	$7.97	$7.97 Fixed fee	$7.97	$7.97
C	$7.80	$7.80 Fixed fee	$7.80	$7.80
D	$8.07	$8.40 if less than $100	$9.70	$8.74
E	$7.76	$9.35 if less than $125 $14.02 if more than $125	$9.94	$8.42
F	$7.86	N/A	$8.66	$8.06

Source: Canadian Council of Legislative Auditors - Health Study Group

(1) & (2) Average fee is the total dispensing fees paid for one drug divided by total number of claims for that drug.
(1) Lowest Average Fee - the jurisdiction's lowest individual average dispensing fee for one of the 20 drugs.
(2) Highest Average Fee - the jurisdiction's highest individual average dispensing fee for one of the 20 drugs.
(3) Average for All 20 Drugs - the average of all the jurisdiction's average dispensing fees for all 20 drugs.

- Manitoba's overall average dispensing fee of $9.10 for those top 20 brand name drugs, was the highest of all jurisdictions surveyed. The average fee for those 20 brand name drugs is approximately the same as calculated for Pharmacare's overall average for 2002/03 in **Figure 8**. Those jurisdictions without dispensing fee limits or with graduated fees had higher average fees than those with fixed dispensing fees.

- Pharmacists are allowed to charge dispensing fees at a level they feel appropriate with guidelines set by the Manitoba Pharmaceutical Association, i.e., maximum fee levels are not currently legislated in Manitoba.
- In our review of a different sample of drugs extracted from the 2005 DPIN system, the dispensing fees reimbursed by Pharmacare ranged from $0 to $300. It appeared that dispensing fees in this sample were often charged as a percentage of the cost of the drug, so the higher the drug cost, the higher the dispensing fee may be. We noted an example of a prescription for a $7,320 drug cost which incurred a $300 dispensing fee. Sometimes dispensing fees were not charged at all. We were advised that there may be fees charged for other drugs received at the same time and the pharmacist may waive the fee on the lower priced drugs.
- To assess the financial impact of dispensing fees, we calculated the actual dispensing fees paid in Manitoba for dispensing the group of top 20 drugs. The total cost of those 20 drugs to Pharmacare, for 2002/03 was $23,296,444. The total dispensing fees for those 20 drugs were $4,142,731 or 17.6% of the cost of the drug for that period.
- **Figure 8** illustrates the Average Dispensing Fees for the Pharmacare Drug Program from 2000 to 2005, which has risen from $7.58 to $10.88 or 43.5% in just 5 years. The rate of increase was well above the rate of inflation for that period.

FIGURE 8

Average Dispensing Fees - Rate of Increase Over Five Years - 2000 to 2005

	2000/01	2001/02	2002/03	2003/04	2004/05
Average dispensing fee	$7.58	$8.30	$9.04	$10.06	$10.88
Percent annual increase	7.1%	9.5%	8.9%	11.3%	8.2%

Source: Manitoba Health

- There were no regulations or policies in place to prevent prescription splitting (preparing two or more separate prescriptions to fill one order and thereby charging dispensing fee on each one) other than a regulation which required dispensing no more than 100 days supply. There also did not appear to be any monitoring by Manitoba Health of those practices.

5.5 IMPACT OF COMMERCIAL MARKETING PRACTICES

Audit Criteria

Provincial drug program officials recognized that drug manufacturers may influence the prescribing of newer more expensive drugs through commercial marketing practices. Manitoba Health should analyze commercial marketing practices to determine if they have an impact on the Pharmacare program and strategies.

Specifically, we considered whether:

- Commercial marketing practices had an impact on the overall cost of drugs for the Pharmacare program (**Section 5.5.1**); and
- Manitoba Health took action to reduce any significant impact of commercial marketing practices on the Pharmacare program (**Section 5.5.2**).

5.5.1 Impact Of Commercial Marketing Practices May Have Contributed To An Increase In Pharmacare Costs

OBSERVATIONS

- Manitoba Health recognized that pharmaceutical companies could exert some influence on physicians' prescribing practices through incentives, such as rebates, and marketing to consumers. Examples which Manitoba Health identified included:
    - Promoting new patented drugs over older established and often generic drugs, may result in an increase in the volume and the cost of specific drugs; and
    - Manufacturers may sell certain drugs at a lower cost to hospital pharmacies compared to some retail pharmacies. That practice may introduce the drugs to the physician's prescribing practices, increasing the volume of those drugs and the related costs to Pharmacare. A hospital patient and their physician may feel more comfortable with the drugs used in their hospital stay and may continue with those drugs once outside the hospital. This practice is similar in other jurisdictions as noted below.
- The practice of pharmaceutical companies selling drugs to hospitals at a much lower cost than to Pharmacare can be viewed as marketing practices, as noted in the Report of the Auditor General of Nova Scotia's Pharmacare and other Drug Program (Sec 7.55):

> *"... drug manufacturers tend to use acute care sector as a means by which to introduce potential customers to their products and as such provide their products to acute care institutions at prices lower than those charged to Pharmacare programs. The Department of Health indicates that these prices are exclusive to the acute care sector and therefore not available to the public Pharmacare Programs."*

- Manitoba Health officials indicated that they had been made aware of specific instances where a large volume of new and more expensive drugs were being used for more days which may have been due to commercial marketing practices. That large volume of more expensive drugs results in an increase in volume and costs of drugs to Pharmacare.

5.5.2 Inadequate Monitoring Of Commercial Marketing Practices

OBSERVATIONS

- There was no evidence of a planned approach by Manitoba Health to analyze and take action in response to the potential impact of marketing practices on Pharmacare. Without monitoring and analysis, Manitoba Health cannot determine whether commercial marketing practices are influencing the cost of drugs or take action to reduce any impact.
- Several provincial jurisdictions in Canada had established processes to increase the physicians' awareness of concerns over prescribing new more expensive drugs versus established lower priced generic drugs (see **Section 6.0**). Some of those processes were:
    - Nova Scotia Department of Health attempts to influence prescribing practices of physicians by obtaining and analyzing drug use information; and
    - Quebec has legislation and whistle-blower laws on inappropriate commercial practices of manufacturers.

5.6 DRUG PRICE CONTROLS AND AUDITING

Audit Criteria

Prices of drugs should be followed-up and analyzed and, if necessary, audited. Specifically, we considered whether:

- **Controls were in place to ensure drug prices paid to pharmacies are in line with Pharmacare's pricing policies (Section 5.6.1); and**
- **There was periodic analysis of those controls and corrective action is taken where necessary (Section 5.6.2).**

5.6.1 Maximum Allowable Drug Price Was Established In DPIN

OBSERVATIONS

- The DPIN system controls only allowed the payment of the price established for a drug. If a pharmacy had a concern that the price being reimbursed was incorrect, they had to contact Manitoba Health to review the situation with one of the staff authorized to make price changes. Any changes made were recorded in DPIN, which also recorded the Manitoba Health staff user identification number of the person who made the change.

- To assess DPIN price controls, we requested a sample of transactions that identified when the price paid was different than the price set in DPIN. A sample of the largest variances recorded in DPIN in the current system (last six months) was reviewed to ensure that either DPIN application controls or other review controls were in place to ensure the proper functioning of that payment control.
- We also tested the prices for a sample of drugs to identify those with interchangeable drug prices and ensure the lowest price was used in all cases.
- For both of these samples, we verified that the lowest price in DPIN was in fact the price that was applied in DPIN.

5.6.2 Price Controls Not Periodically Analyzed

OBSERVATIONS

- There was no evidence of periodic analysis to assess the accuracy of drug price information input to DPIN nor the effectiveness of DPIN system controls in ensuring the lowest cost drug is the one that is paid for by Pharmacare.
- There was no evidence of monitoring performed by Manitoba Health of the actual price paid for selected prescriptions as compared to the prices recommended by MDSTC and approved by the Minister. MDSTC minutes reflected discussion that Manitoba Health should request manufacturers to send them notification of any price change for review. There was a concern that Manitoba Health did not follow up on the information related to price increases.

6.0 Physician Prescribing Practices and Monitoring of Drug Use – Observations and Conclusions

We reached the following overall conclusions on the physician prescribing practices and monitoring of drug use objective and criteria:

Audit Objective and Criteria	Conclusions
To assess whether Manitoba Health monitored the quality and relevance of drug use, and encouraged appropriate and economical prescribing and dispensing practices in relation to Pharmacare. In particular, whether: • Prescribing practices of physicians were monitored by Manitoba Health to determine whether they were appropriate and economical, in regards to providing the most cost effective treatment option. • Controls were in place to encourage safe prescribing practices and Manitoba Health monitored that these practices were followed by physicians. • Adequate procedures were in place to monitor and analyze drug use, and where necessary, inform the physicians and pharmacists involved when potential problems were identified.	Overall Manitoba Health requires significant improvement in their monitoring of the quality and relevance of drug use and their encouragement of appropriate and economical prescribing and dispensing practices. • Manitoba Health did not actively promote the most appropriate and economical prescribing practices to physicians through the communication of best practice information. As a result, Manitoba Health had limited means to attempt to control program costs through influencing physicians prescribing practices. • Manitoba Health did not monitor prescribing practices of physicians nor focus on collaborating with key stakeholders to enhance prescribing and drug use practices. • Manitoba Health did not have a procedure for monitoring how a pharmacist responds to system warnings (e.g., unsafe drug combinations) from the DPIN system. • Manitoba Health did not have adequate processes in place to be able to monitor and analyze drug use within Pharmacare to ensure the most appropriate and economical prescribing and dispensing of drugs. • Manitoba Health did not use the extensive amount of information that is collected by DPIN to regularly and systematically identify patterns of inappropriate drug prescribing, dispensing and use. Manitoba Health missed the opportunity to better use information to highlight health risks to drug recipients, such as, prescriptions for excess drugs or narcotic and controlled drugs.

In reaching the overall conclusions, we examined three key areas that relate to the prescribing and dispensing of drugs:

6.1 Guidance and Monitoring of Physician Prescribing Practices;
6.2 Controls Over Prescribing Practices; and
6.3 Monitoring and Analysis of Drug Use.

Detailed audit criteria and observations are presented in the related sections.

6.1 GUIDANCE AND MONITORING OF PHYSICIAN PRESCRIBING PRACTICES

Audit Criteria

Prescribing practices of physicians should be monitored by Manitoba Health, to determine whether they are appropriate in relation to the current standards of care, and economical in regards to providing the most cost effective treatment option. Specifically, we looked to find whether:

- Manitoba Health provided guidance to physicians on appropriate and economical prescribing practices (**Section 6.1.1**); and
- The prescribing practices of physicians were monitored by Manitoba Health to ensure that the most appropriate and economical drugs are being prescribed by physicians (**Section 6.1.2**).

6.1.1 Manitoba Health Did Not Provide Sufficient Guidance To Physicians On Appropriate And Economical Prescribing Practices

OBSERVATIONS

- Manitoba Health tried to contain the cost of Pharmacare by managing the listing of drugs which were eligible for payment under the program (see **Section 5.0**). However, Manitoba Health did not appear to actively promote the most appropriate and economically efficient prescribing practices to physicians or promote other cost containment measures.
- Pharmaceutical companies actively promote the use of newer (generally more expensive) drugs to prescribing physicians. Physicians have a very large number of drugs to choose from when prescribing for a patient. In the absence of any source of unbiased information regarding the most economical and effective prescribing practice, physicians may rely on the information provided by the drug manufacturers.
- Some other jurisdictions have sought to contain the growth in the cost of Pharmacare by promoting the most cost effective prescribing practices through educational programs for physicians. These programs sought to provide physicians with unbiased, critically appraised information about best practices related to the prescribing of drugs for various conditions. An example of this was by promoting the use of generic drugs first in treating a patient (generic drugs are generally less expensive than newer, patented/brand name drugs).
- Prior to 2004, two programs were funded by Manitoba Health and run by the Manitoba College of Physician and Surgeons (MCPS) which related to the provision of guidance to physicians regarding appropriate and economical prescribing practices. These programs were:

  - *Manitoba Prescribing Practices Program (MPPP)*
    This program focused on monitoring and evaluating the prescribing of narcotic and controlled drugs.
  - *Manitoba Clinical Practice Guideline Program (MCPGP)*
    This program focused on providing best practice information to physicians regarding treatment of some of the most prevalent health conditions which may be encountered by patients. The program provided an overall suggested treatment of a condition (e.g., diabetes) and only had a small component which focused specifically on prescribing practices which would relate to the treatment of the condition (e.g., the particular medicine to be prescribed in a given circumstance).

- Officials of Manitoba Health advised that negotiations between Manitoba Health and the MCPS resulted in the end of the MCPGP in 2004, and the transfer of the administration of the MPPP to the MPhA in 2005.
- Manitoba Health stated that the Canadian Optimal Medication and Prescribing Utilization Service (COMPUS) was being set up nationally under federal/provincial/territorial health agreements and was to address this issue. Officials from Manitoba Health were participating in COMPUS. At the date of the completion of our fieldwork, COMPUS was in the process of hiring staff and developing processes for collecting, evaluating, and disseminating evidence-based best practice information strategies and tools for the national departments of health. The first project planned by COMPUS relates to the use of pharmaceuticals in the treatment of stomach ailments and was scheduled for release in the fall of 2005.

6.1.2 Manitoba Health Did Not Adequately Monitor The Prescribing Practices Of Physicians

OBSERVATIONS

- The CCAF and the Canadian Healthcare Association, in their 2004 publication, *Excellence in Canada's Health System - Principles for Governance, Management, Accountability and Shared Responsibility* noted that:

  > *"Canada's Health system is best served by coherent direction, informed decision-making and clear goals that are shared among those responsible for decision making."*

- In Manitoba, the individual medical professional and their professional bodies were responsible for ensuring that physicians and pharmacists were current with the most up to date clinical information regarding best prescribing practices.
- Continuing education requirements for physicians and pharmacists were administered by the Manitoba Medical Association, the MCPS, and the MPhA.

- Manitoba Health relied on the professional medical governing bodies to ensure compliance with their professional standards. In this regard, Manitoba Health did not participate in, review, nor monitor how the information regarding prescribing practices were communicated to and followed by physicians and pharmacists. As a result, Manitoba Health had insufficient means to assess if best prescribing practices were being followed by physicians in Manitoba.

6.2 CONTROLS OVER PRESCRIBING PRACTICES

Audit Criteria

Controls should be in place to encourage safe prescribing practices and Manitoba Health should monitor that these practices are followed by physicians (Section 6.2.1).

6.2 1 Opportunities Exist To Improve Monitoring Controls Over Prescribing Practices

OBSERVATIONS

Drug Program Information Network (DPIN)

- Manitoba Health maintains the DPIN computer system - an online, real time computer network system which records and assesses the safety of prescriptions at the time they are dispensed.
- DPIN is linked to all pharmacies in Manitoba. DPIN was originally established in 1994 as one of the first integrated – real time Pharmacare management systems, and as per Manitoba Health it was one of the most comprehensive systems in use nationally.
- In Manitoba, DPIN is the only comprehensive database of drug use centrally linked with all pharmacies. Only two other provinces (British Columbia and Saskatchewan) maintain databases which capture retail pharmacy prescription information. In many other jurisdictions in Canada, retail pharmacies used their own company operated systems which were not centrally linked and could only access information for prescriptions filled in their pharmacies.
- DPIN facilitates two functions in the Pharmacare program:
    - **Financial**: Payment to pharmacist and evaluating and recording of patient eligibility and deductible; and
    - **Drug use and safety**: Recording client drug use and warning of potential adverse consequences of drug use.
- Manitoba Health's stated objectives for DPIN were to:
    - Reduce adverse drug interactions and reactions;
    - Reduce hospitalization as a result of adverse drug events;

  - Optimize the prescribing of drugs;
  - Promote better communication between pharmacists, prescriber and patients;
  - Discourage "double doctoring" and fraudulent use of drugs;
  - Facilitate drug/health outcomes measurement and management; and
  - Streamline administrative procedures.

- One of the most significant factors in ensuring safe and effective prescribing practices by physicians is ensuring that physicians know the entire drug use profile of the patient. Except for physicians in hospitals, most physicians do not have direct access to the DPIN system at the time of writing a prescription. DPIN allows a pharmacist to review all drugs dispensed to a patient over the last six months. The pharmacist who fills a prescription is responsible for verifying that all physicians prescribing to a patient are aware of any potential drug therapy conflict.

- DPIN supports the safety of prescribing practices of physicians by assessing the prescription of a drug against set criteria at the time the pharmacist fills the prescription. To do this, DPIN uses a purchased third party software program.

- The controls built into DPIN assess the appropriateness and safety of prescriptions by immediately detecting and issuing a warning to the pharmacist in situations such as:

  - where two or more drugs prescribed concurrently may result in an adverse drug interaction;
  - where duplicate drugs are prescribed by one or more physicians;
  - where the prescribing of drugs suggest the potential for duplicate therapy by one or more physicians;
  - potential for inappropriate dosage of a prescription; and
  - other situations which would indicate inappropriate or unsafe drug prescribing and dispensing.

Entry of Prescriptions into DPIN is Voluntary

- All pharmacies in Manitoba are linked to the DPIN computer system. DPIN tracks a person's drug use by their Personal Health Identification Number (PHIN) which Manitoba Health assigns to all Manitobans eligible to receive health benefits. Pharmacists normally enter all prescriptions into DPIN, regardless of whether the prescription is eligible for payment by Pharmacare or not. Entering all prescriptions into DPIN, even though some may not be eligible for payment under Pharmacare, ensures that the safety controls (warnings) of DPIN are highlighted for any prescription filled.

- A person may specifically request that the pharmacist not enter the prescription into DPIN, as DPIN is voluntary for the person filling a prescription. However prescriptions must be entered into DPIN in order to obtain Pharmacare reimbursement. Therefore anyone who requested the pharmacist not to enter their prescription into DPIN would have been required to pay the full cost themselves.

- Not entering a prescription into DPIN would also by-pass the DPIN system controls in place that provide for the safety and appropriateness of the prescription. One potential consequence of DPIN being voluntary is that people seeking sources for high risk drugs such as narcotic or controlled drugs could potentially by-pass the controls in place that detect multiple prescriptions or duplicate therapy (see **Section 6.3.1**).
- Manitoba Health had no means to identify how many prescriptions were filled in Manitoba which had not been entered into DPIN.

DPIN Safety Controls/Warnings for Pharmacists

- When DPIN detects a potential problem with a prescription, it generates a warning for the pharmacist filling the prescription. That pharmacist is responsible for resolving any warnings. The pharmacist uses their professional judgment to determine which warnings need to be communicated to the prescribing physician(s).
- The pharmacist decides how to resolve any warnings based on their professional knowledge and judgment; and/or by questioning the person seeking to fill the prescription; and/or consulting with the physician who wrote the prescription.
- Only two warning codes generated by DPIN require the pharmacist to respond on DPIN to indicate how the warning was resolved, before the prescription can be filled. These are:
  - Duplicate drugs dispensed from a different pharmacy; and
  - Duplicate therapy dispensed from a different pharmacy.

  In these cases the pharmacist also documents, in the pharmacy files, how the warning was resolved. No other warnings require the pharmacist to document how the warning was resolved.
- If the dispensing pharmacist does not inform the prescribing physician of a warning generated by DPIN, the physician may not be aware of the potential drug warning that was generated by the system for his/her patient.

Consolidated DPIN Safety Warnings Not Monitored By Manitoba Health

- We determined that in 2003, DPIN generated 5,573 warnings to pharmacists for the highest level of severity for adverse drug interaction (two or more drugs that if taken together could result in a serious health risk).
- MPhA pharmacy standards of practice mandate that a pharmacy provider must appropriately respond to the DPIN warnings. Under the current DPIN system, warnings for adverse drug interactions do not require the pharmacist to respond and record on the system how the warning was resolved.

- Manitoba Health depends on the pharmacist to resolve warnings at the time that they are generated. However, Manitoba Health did not monitor, nor analyze, the consolidated records of warnings. Although pharmacists are aware of individual warnings, Manitoba Health's DPIN is the only source of consolidated warning information.
- If Manitoba Health had procedures in place to monitor overall warnings, they would be able to identify potential situations where:
  - two or more physicians were writing incompatible prescriptions for the same patient without being aware of the other prescribing physician or prescription; or
  - a single physician was prescribing incompatible drugs.
- A regular analysis of the warnings generated by DPIN may have identified areas of concern for communication to the physicians and pharmacists involved. For example, it may be possible to identify if a certain number of physicians are responsible for a disproportionate number of warnings being generated, in such serious areas as adverse drug interactions. This could be an indication of inappropriate prescribing practices.

6.3 MONITORING AND ANALYSIS OF DRUG USE

Audit Criteria

Adequate procedures should be in place to monitor and analyze drug use, and where necessary, inform the physicians and pharmacists involved when potential problems are identified. Specifically we looked to find whether:

- There was an analysis of the data to identify poor prescribing practices such as over-prescribing and potential adverse drug interaction;
- There was a process to analyze the prescription of narcotic and controlled drugs and drugs recognized to have a history of abuse, in order to identify cases of excess use or prescribing by physicians to patients which ultimately may have been harmful to the health of the patient; and whether
- There was a process for informing the involved health care providers based on the findings from data analysis.

6.3.1 Inadequate Procedures Are In Place For Monitoring And Analysis Of Drug Use

OBSERVATIONS

Responsibility for Monitoring Drug Use

- Manitoba Health was not required under any Act to be responsible for monitoring or analyzing drug use in order to identify potential instances of poor prescribing practices or situations which indicate the potential of harm to the recipients of drugs.
- Although DPIN produced safety control warnings, DPIN did not produce on line, real time warnings to the dispensing pharmacist related to potential over prescribing or over use of drugs. However, as DPIN is the only system within the provincial health care system that collects the information which can detect these situations, Manitoba Health could utilize the information to optimize the prescribing of drugs and the health outcomes of Manitobans where possible.

Data Collection and Analysis

- Manitoba Health did not monitor and analyze drug use data. DPIN collected extensive data regarding the prescribing, dispensing, and use of prescription drugs in Manitoba. This is the most comprehensive data base of drug use information which exists for Manitobans. However, Manitoba Health made very little use of this information.
- A similar situation existed within the Federal drug benefit programs. The Auditor General of Canada's November 2004 Report entitled, *Management of Federal Drug Benefit Programs,* noted that the federal drug programs are "data rich but information poor." The Report also noted that:

  > *"Analyzing how drugs are being used is critical in supporting the provision of good health care. Experts ...consider the analysis of this information to be an important element in the management of pharmacare programs and believe that such analysis can have a significant impact on the quality of health care."*[8]

- DPIN is a system implemented to provide clinical and fiscal adjudication. Claims level data which is available to DPIN is not equivalent to health outcomes data which requires linkage to other data bases and or other information sources.
- There are a limited number of appropriateness of drug use measures which can be evaluated by DPIN prescription data alone, such as presence of drug interactions, duplication of prescription therapy, and polypharmacy.

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[8] *Report of the Auditor General of Canada*, Chapter 4, Management of Federal Drug Benefit Programs, November 2004.

Identification Of Potentially Poor Prescribing Practices

Following are examples of two areas where the medical profession has identified that drug use has a direct effect on the health outcomes of patients. Manitoba Health could have addressed these two areas through systematic monitoring, analysis of existing data, and communicating results with medical professionals. The examples are:

- Excessive prescription drug use; and
- Prescribing and monitoring of narcotic and controlled drug use.

Excessive Prescription Drug Use

- Excessive prescription drug use (Polypharmacy) has been defined as taking six or more different medications at the same time. While there are some instances where multiple medications are required for proper disease management, there is evidence that people taking six or more medications are at increased risk for medication related adverse events.
- The Manitoba Center for Health Policy in its March 2005 report on High-Cost Users of Pharmaceuticals noted the following:
    - *"The receipt of multiple medications, known as Polypharmacy, is a risk factor for hospital readmission, prolonged length of stay and mortality.*
    - *Half of high-cost users see three or more family physicians a year. This is a concern because inappropriate, sometimes fatal, drug combinations are more common among people seeing multiple health care providers".*[9]
- For **Figures 9, 10 and 11**, total number of cases in DPIN represents all prescriptions dispensed in Manitoba which were entered into the DPIN system. The total cases reimbursed by Pharmacare represents only those prescriptions for which Pharmacare has jurisdiction.
- To explore the ability of the existing DPIN system to identify situations where there is a potential problem regarding Polypharmacy, we obtained an analysis of the 2003 archived DPIN data base. The following data presented in **Figures 9, 10 and 11** is intended as an example of the potential information which can be derived from the DPIN system. The analysis does not account for any differences between consecutive and concurrent utilization. To confirm problems regarding Polypharmacy and potentially dangerous drug use, Manitoba Health would need to perform further analysis distinguishing concurrent and consecutive drug use. With the data available to us we were able to identify the following:

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[9] Manitoba Center for Health Policy, *High-Cost Users of Pharmaceuticals: Who Are They?*. March 2005.

FIGURE 9

Key Data Indicators of the Potential Excess Prescription Drug use Over a One Year Period (2003)

Indicator*	Total Number of Cases in DPIN Database 2003**	Total Cases Reimbursed by Pharmacare 2003**
People receiving more than 6 drugs	179,631	49,164
People receiving more than 15 drugs	31,766	7,213
People receiving more than 50 drugs	130	6

Source: Manitoba Health

* Indicator derived from Office of the Auditor General of Canada, November 2004 Report, Chapter 4, Management of Federal Government Drug Program.

** These figures do not distinguish between concurrent and consecutive drug use.

- The health risk associated with Polypharmacy increases with the age of the patient. For people over the age of 65, "some experts consider that when the number of drugs exceed seven, the risk of serious drug reactions approaches 100%".[10]
- Although there are no DPIN warnings provided to alert pharmacists in an on-line real time manner, currently the DPIN system provides pharmacists with information on a person's drug history, which is available for the pharmacist to review if they wish to assess concerns regarding a person's concurrent drug use at the time of dispensing.

FIGURE 10

Key Data Indicators of the Potential Excess Prescription Drug use Over a One Year Period (2003)

Indicator*	Total Number of Cases in DPIN Database 2003**	Total Cases Reimbursed by Pharmacare 2003**
People over 65 receiving more than 7 drugs	61,796	27,496

Source: Manitoba Health

* Indicator derived from Office of the Auditor General of Canada, November 2004 Report, Chapter 4, Management of Federal Government Drug Program.

** These figures do not distinguish between concurrent and consecutive drug use.

- The results of our analysis of existing DPIN information suggested that there may have been a large number of Manitobans whose health might have been at risk due to being prescribed excess drugs. Further analysis that distinguishes concurrent and consecutive drug use is required to confirm potentially dangerous drug use.
- The above results suggest that there may have been a significant number of cases where:

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[10] *Report of the Auditor General of Canada*, Chapter 4, Management of Federal Drug Benefit Programs, November 2004.

  - two or more physicians were prescribing to a single patient where they were unaware of the other physician(s); or
  - that a single physician may have been prescribing a number of drugs which had the potential for adverse interaction.

- Manitoba Health did not analyze the DPIN database to:
  - identify such cases;
  - determine if the controls in place within the DPIN system generated warnings in relation to drug interactions in these situations; or
  - determine how the warnings if issued, were resolved by the pharmacist filling the prescription.

Prescribing and Use of Narcotic and Controlled Drugs

- To explore the ability of the existing DPIN system to collect data relating to the prescription and use of narcotic and controlled drugs, we requested an analysis from Manitoba Health of the 2003 DPIN database, and obtained the results as shown in **Figure 11** below.
- The parameters we used were also used by the Auditor General of Canada in the audit of federal drug programs. We confirmed, by inquiry with a medical physician knowledgeable in the field of surveillance of narcotic prescribing, that these are indicators which could highlight potential problems with narcotic prescription and use, and could indicate a need to follow up with the prescribing physicians.

FIGURE 11

Key Indicators of Potential Drug Abuse Activity Using Narcotic and Controlled Drugs (2003)

Indicator*	Total Number of Cases in DPIN Database 2003	Total Cases Reimbursed by Pharmacare 2003
People receiving a narcotic or controlled drug and: - Using 4 - 6 physicians and 4 - 6 pharmacies	226	101
- Using 7 - 10 physicians and 7 - 10 pharmacies	3	2
- Using more than 10 physicians and more than 10 pharmacies	1	1

Source: Manitoba Health
* Indicator derived from Office of the Auditor General of Canada, November 2004 Report, Chapter 4, Management of Federal Government Drug Program

- The preceding results noted in **Figure 11**, for the column titled, *Total number of cases in DPIN Database 2003*, represent all Manitobans whose prescription use was recorded in DPIN in 2003. This did not include drug prescriptions dispensed to patients admitted to Hospitals, Personal Care Homes and those people who had received prescriptions from retail pharmacies who had specifically requested that their prescription information not be entered into the DPIN system.

- The results of our analysis suggest that there could have been some Manitobans whose health might have been at risk due to the level of prescription and use of narcotic and controlled drugs.
- Additionally, there were other drugs which were not classified as narcotic and controlled drugs, but were identified to have a high potential for abuse or diversion. Drugs such as Benzodiazepines and Tylenol 3 were not being monitored.

Monitoring Of Narcotic And Controlled Drug Use

- Manitoba Health depended on third parties, such as the professional associations for doctors and pharmacists in Manitoba for the monitoring of narcotic and controlled drug use. These include the Manitoba College of Physicians and Surgeons (MCPS) and the Manitoba Pharmaceutical Association (MPhA). Prior to 2005, monitoring was carried out under a formal agreement with the MCPS, who continued to monitor using the Manitoba Prescribing Practices Program (MPPP), until May 2005 when the MPhA became the administrators of the new program for the monitoring of narcotics and controlled drug use.
- Manitoba was one of only five jurisdictions in Canada that had specific programs for monitoring the prescribing and dispensing of narcotic and controlled drugs.

Prior Monitoring Of Narcotic And Controlled Drug Use

- MPPP which operated until 2005 was administered by MCPS. Part of the MPPP involved administering the issuance of Triplicate Prescription Pads (TPP) and reconciling their use. These prescription pads were pre-numbered and were required for any physician to write a prescription for any narcotic or controlled drug. Additionally, the MCPS as part of the MPPP would obtain an abstract of the DPIN system from Manitoba Health, to reconcile the use of the TPP and to perform certain analysis of the pattern of prescribing and use of narcotic and controlled drugs.
- In 2005, the MCPS ended their involvement in the MPPP. Manitoba Health was establishing a new program for the monitoring of narcotic and controlled drugs which was to be carried out through an agreement with the MPhA as described below.
- The last annual report of the MPPP was issued by the MCPS in 2002. In that report, the MCPS indicated that through analysis of the DPIN data base, the MPPP identified the following concerns and had taken the following action:
    - 72 potential cases which indicated questionable prescribing practices by physicians and/or improper drug use by patients:
        - An example of this would be that a patient had been receiving prescriptions for narcotics for a period of time that was in excess of the guidelines of best practice per the Compendium of Pharmaceutical Service; and

        - In these cases, the MPPP program notified the physician that a patient's drug use was outside the normal prescribing practice and asked for a review of the patient's treatment plan.
    - 314 cases of what appeared to be atypical medication usage by a patient (outside of the expectation of the program):
        - An example of this would be that a patient was identified who was receiving prescriptions for narcotic or controlled drugs from more than one physician; and
        - In these cases the physicians were contacted by the MPPP to inform them of the situation, and were required to respond to the MPPP with an explanation of the situation and how it was resolved.
- These cases were identified by conducting an analysis of the historic record of the DPIN database. As a result, these cases represent instances which apparently were not detected by the controls in place in the DPIN system or the TPP system at the time that the prescription for a narcotic or controlled drug was originally dispensed.
- The MPPP program was run internally by the MCPS and while Manitoba Health provided the DPIN system data for analysis, Manitoba Health was not directly informed of specific concerns that were detected except when specifically notified by the MCPS.

New Monitoring Program For Narcotic And Controlled Drugs In Manitoba

- Manitoba Health and the MPhA proposed that effective March 2005, the system of monitoring the prescribing and dispensing of narcotic and controlled drugs in Manitoba be transferred to the MPhA. The membership of the MPhA agreed to the required changes to *The Pharmaceutical Act* as of March 23, 2005. The specific program was being designed and was subject to government approval. At the time of completion of our audit, this program was in place.
- The proposed new monitoring system was designed as what was being called an "at source risk management system". The dispensing pharmacist would be responsible for evaluating a patient's drug profile and history at the time that a prescription for a narcotic or controlled drug is filled. The pharmacist would also be required to identify potential problems and communicate with the prescribing physician(s) to resolve any concerns. Physicians prescribing narcotic and controlled drugs who may have questions or concerns regarding a patient's drug profile or history would need to contact a pharmacist to request a review of the patient's drug use from the DPIN system.

7.0 Reporting to the Legislature – Observations and Conclusions

We reached the following overall conclusions in relation to audit objective and criteria on reporting to the legislature:

Audit Objective and Criteria	Conclusions
To assess whether there is adequate reporting on Pharmacare's performance. In particular, whether: • The performance information reported by Pharmacare in its annual report should be consistent with government's directives on performance reporting as well as *CCAF Principles of Performance Reporting*.	Manitoba Health's 2003/04 Annual Report which contained information on Pharmacare was not adequate. The section on Pharmacare in the Annual Report did not contain a sufficient amount of the right type of information to enable the reader to draw conclusions on how well Pharmacare is functioning nor did the information provide sufficient transparency and accountability. • The performance information on Pharmacare in the Annual Report only partially fulfilled the *Departmental Annual Reports Instructions* issued by the Comptroller's Division of the Department of Finance. • The information on Pharmacare which was provided in Manitoba Health's 2003-2004 Annual Report is not consistent with the *CCAF Performance Reporting Principles*.

In reaching the overall conclusions, we examined the quality of performance reporting.

Detailed audit criteria and observations are presented in the section that follows.

7.1 QUALITY OF PERFORMANCE REPORTING

Audit Criteria

- The performance information reported by Pharmacare in its annual report should be consistent with government's directives on performance reporting as well as *CCAF Principles of Performance Reporting* (see **Section 7.1.1** and **7.1.2**).
- In terms of Government's directives on annual reporting these are contained in *Departmental Annual Reports Instructions* issued by the Comptroller's Division of the Department of Finance. We used these directives to determine whether Pharmacare is complying with Government expectations regarding the content of annual reporting.

- CCAF is a national, non-profit research and education foundation which researches public sector accountability, management and audit issues, and developed a set of nine *Principles of Performance Reporting* based on extensive consultation with legislators, managers and auditors. We used the *CCAF Principles of Performance Reporting* as the basis for assessing the content and quality of information on Pharmacare that is contained in Manitoba Health's 2003/04 Annual Report. The *Principles of Performance Reporting* are summarized in **Figure 12.**

7.1.1 Reporting Not Consistent With Government Instructions

OBSERVATIONS

- In relation to the Government *Annual Report Instructions*, the section on Pharmacare in the Manitoba Health 2003/04 Annual Report focused on a presentation of expenditures. The section on Pharmacare did not cover key aspects of the type of information described in the Instructions. Among the aspects not included on Pharmacare in the Annual Report are the following which are contained in the Instructions:
    - Relating planned activities and expected results to actual accomplishments (p. 3); and
    - Explaining significant operational variances in terms of the external and internal factors that account for the deviations from expected results (p. 12).
- Making performance information more in-line with *Departmental Annual Reports Instructions* will better communicate the public benefit that Pharmacare is achieving and will enable a reader to determine the value and contribution of the program. In this way, accountability and transparency would be enhanced.

7.1.2 Reporting Not Consistent With CCAF Principles

OBSERVATIONS

- The section in the Annual Report that deals with Pharmacare identified Pharmacare's overall goal, the deductible amounts, and presented a financial summary of expenditures. However, it lacked virtually all the features of the *CCAF Performance Reporting Principles* in **Figure 12**. For instance, the Manitoba Health 2003/04 Annual Report did not identify key objectives of Pharmacare, or explain key risks and key capacity considerations. There was no comparison between expected and actual results nor was there any comparative information between Pharmacare and prescription drug programs in other jurisdictions. Data on expenditures was not linked to particular objectives.

- Making performance information more in-line with *CCAF's Performance Reporting Principles* which is a recognized standard for government reporting, will better communicate the public benefit that Pharmacare is achieving and will enable a reader to determine the value and contribution of the Program. To facilitate the program's ability to effectively report in relation to the *CCAF Performance Reporting Principles*, it would need to develop specific, measurable objectives of the program in relation to each of its key functions and reporting of actual results compared to expected results.

FIGURE 12

Summary of CCAF Performance Reporting Principles

1. **Focus on the Few Critical Aspects of Performance**
    - focus selectively and meaningfully on a small number of things;
    - centre on core objectives and commitments.
2. **Look Forward as well as Back**
    - set out the goals and how activities contribute to the goals;
    - track achievements against expectations.
3. **Explain Key Risk Considerations**
    - identify the key risks;
    - explain the influence of risk on choices and directions and relate achievements to levels of risk accepted.
4. **Explain Key Capacity Considerations**
    - discuss capacity factors that affect the ability to meet expectations;
    - describe plans to align expectations and capacity.
5. **Explain Other Factors Critical to Performance**
    - explain general factors such as changes in the economic, social or demographic environment that affect results;
    - discuss specific factors such as standards of conduct, ethics, and values, or performance of other organizations that influence performance;
    - describe unintended impacts of activities.
6. **Integrate Financial and Non-Financial Information**
    - explain the link between activities and desired results;
    - show spending on key strategies and explain how changes in spending affect results.
7. **Provide Comparative Information**
    - provide comparative information about past performance and about the performance of similar organizations when relevant, reliable and consistent information is reasonably available.
8. **Present Credible Information Fairly**
    - present information that is relevant and accurate in a manner that is understandable;
    - explain management's involvement, judgment, and basis for interpretation of performance.
9. **Disclose the Basis for Reporting**
    - explain the basis for selecting the few critical aspects of performance on which to focus;
    - describe changes in the way performance is measured or presented;
    - set out the basis on which those responsible for the report hold confidence in the reliability of the information being reported.

8.0 Recommendations for Manitoba Health

Program Management

Program Direction

- That a comprehensive plan be developed for the strategic direction/ reforms for Pharmacare. The strategic direction for Pharmacare should include:
    - specific objectives with targets that are measurable;
    - clear policy goals/objectives in relation to all key aspects or core services;
    - goals/objectives, policies and procedures that support Pharmacare's key outcomes as well as wider outcomes of relevant legislation, and those of Manitoba Health, and Government;
- That the most feasible approach to ensuring that the policy function is adequate for the needs of Pharmacare be identified and implemented; and
- That Manitoba Health conduct regular reviews of its key goals and principles.

Performance Information

- That a performance measurement system be developed that will provide Manitoba Health with data that relates to how efficiently and effectively Pharmacare is being delivered.

Program Monitoring and Evaluation Practices

- That the key aspects of Pharmacare for which to institute performance measurement be identified and a well defined protocol be developed for the collection of performance data and the preparation of performance reports;
- That an evaluation framework be developed and implemented that will guide the undertaking of periodic evaluations of key aspects of Pharmacare's performance, including taking corrective action when necessary based on evaluation results; and
- That there be follow-up on evaluations with a documented plan that articulates:
    - where corrective action will be taken, when and how;
    - which proposals require further consideration, when that will be undertaken and how; and
    - which proposals are not considered appropriate for implementation and the rationale for not proceeding with them.

Compliance With Legislation

- That a process for identifying the degree of risk associated with non-compliance with each aspect of the legislation, regulations, and policies be developed and a strategy for cyclically monitoring compliance in relation to the level of risk identified by management be implemented.

Drug Selection And Cost

Drug Assessment and Selection

- That a standard approved policy and procedures be identified to be used to assess drugs and manage the Formulary; and
- That actual cost savings achieved be analyzed and, if different than proposed cost savings result, the inclusion of those drugs in the Formulary be reassessed.

Periodic Review of Drugs on the Formulary

- That periodic reviews of the listed drugs in the Formulary be conducted that would include identifying and removing discontinued drugs that no longer provide the most cost effective and therapeutic value; and
- That the findings and recommendations of those reviews and follow-up be documented to ensure that any action recommended is in fact carried out.

Fast Tracking Changes to the Formulary

- That a fast tracking process be implemented to put the more cost effective drugs onto DPIN quicker than is presently being done.

Low Cost Strategy

- That pricing strategies be developed and implemented, to achieve more significant savings in the Pharmacare program. Possible strategies include improved controls over markups, industry price changes and increased use of generic drugs; and
- That strategies to control costs on dispensing fees be developed and implemented.

Impact of Commercial Marketing Practices

- That a process to identify, monitor, analyze, and take corrective action (such as moving certain drugs to Part 2 of the Formulary) be established, for the effect of potential impacts of commercial marketing practices on the cost of Pharmacare.

Drug Price Controls and Auditing

- That periodic price tests be performed to assess whether the DPIN system is functioning as prescribed so that prices approved by MDSTC and the Minister, and established in DPIN, are those which are actually paid. Any necessary corrective action should be taken to ensure the appropriate prices are in DPIN.

Physician Prescribing Practices and Monitoring of Drug Use

Guidance and Monitoring of Physician Prescribing Practices

- The CCAF and the Canadian Healthcare Association, in their 2004 publication, *Excellence in Canada's Health System - Principles for Governance, Management, Accountability and Shared Responsibility,* noted that, "Canada's Health system is best served by coherent direction, informed decision-making and clear goals that are shared among those responsible for decision making". Given this, we recommend that:
    - As the sole funder of Pharmacare, Manitoba Health ensure that the best health outcomes for Manitobans and the containment of costs for the Pharmacare Program are maximized. In this light, we recommend that a more proactive role in coordinating, with the professional bodies, any communication of guidance to physicians on the most appropriate and economical prescribing of drugs.

Controls Over Prescribing Practices

- That consideration be given to requiring all prescriptions to be entered into DPIN in order to ensure that the controls to ensure safe and appropriate prescribing are applied for all prescriptions filled; and
- That although the DPIN system provides pharmacists with access to information regarding a person's drug history at the time of dispensing, that Manitoba Health analyze the warnings that are generated by DPIN, in order to identify and assess trends of inappropriate prescribing practices, and establish a procedure for communicating those warnings to physicians on a timely basis.

Monitoring and Analysis of Drug Use

- The CCAF and the Canadian Healthcare Association, in their 2004 publication, *Excellence in Canada's Health System - Principles for Governance, Management, Accountability and Shared Responsibility,* noted that, *"Health system partners need to understand their roles and responsibilities – and governance and management arrangements and practices need to be in place to support the effective discharge of their duties".* In light of this, we recommend that Manitoba Health:
    - Develop programs in cooperation with the professional bodies for physicians and pharmacists, including the Manitoba College of Physicians and Surgeons and the Manitoba Pharmaceutical Association, in order to:
        - Carry out analysis of existing data to identify indicators of concern; and
        - Carry out reviews to ensure that regulations and professional practice guidelines are met, and when in contravention, Manitoba Health is made aware;

- Ensure that physicians and pharmacists receive real time notification from the DPIN system for cases where:
  - Clients receive inappropriate numbers of prescriptions drugs (polypharmacy); and
  - Clients receive inappropriate numbers of narcotic and controlled drugs.

Reporting To The Legislature

Quality of Performance Reporting

- That Manitoba Health's annual reports provide information on Pharmacare that is consistent with Manitoba Finance's Departmental Annual Reports Instructions; and provide information on Pharmacare that is consistent with the CCAF's Principles of Performance Reporting.

Departmental Response

Drug therapy is an important part of an integrated health care system in Canada. Appropriate drug therapy has the potential to improve health outcomes and reduce costs in other aspects of the health system such as acute care and long term care. Drug programs offered by all governments in Canada have been experiencing rapidly increasing costs.

The Manitoba Pharmacare Program is a universal drug benefit program established to protect all eligible residents from financial hardship resulting from expenses for prescription drugs. As a publicly funded program, the Department has a duty to ensure that all funds are spent appropriately.

Fundamentally, the Department has initiated a restructuring process to establish three functional units – Operational Program Management, Professional Services, and Drug Management Policy to facilitate comprehensive, coordinated, and proactive drug benefit program management for the publicly funded drug programs in Manitoba. As a first step, in the fall of 2005, the Department established a Drug Management Policy Unit to provide for focused policy capacity and to develop and implement a strategic policy framework. To that end, the Minister of Health and the Deputy Minister of Health approved the following vision and goals for the Unit:

Vision

- *To establish provincial drug management strategic policy and planning leadership to facilitate the provision of integrated, coordinated, cost efficient and effective, equitable, and sustainable publicly funded drug benefits across the continuum of care in Manitoba.*

Goals

- *To develop and lead the implementation of policies and strategies to increase drug supply chain efficiencies, leading to a lower supply side cost structure.*
- *To contain provincial public drug expenditures by developing and leading the implementation of a demand side drug use policy framework which is expected to yield cost effective prescribing practices, drug utilization, and mitigate non-compliance.*
- *To address gaps in legislation and drug benefit plan design to ensure equitable and affordable access to prescription drug benefits for all Manitobans.*
- *To develop capacity and implement cost effective communication strategies aimed at (1) transferring knowledge and increasing awareness among prescribers, providers, and patients about appropriate drug use, and (2) facilitating consultation and dialogue with stakeholders.*

The two functional areas of Operations Management and Professional Services will also undertake a detailed review and planning process. The review and planning process will be a collaborative effort of the three areas to ensure coordination, integration, and alignment of policy development and drug benefit program service provision. Therefore, collectively, in fiscal 2006/07, the three functional areas will develop a comprehensive plan for the strategic directions/reforms for Pharmacare.

The comprehensive strategic plan will be based on work completed and/or currently under development by the Department, preliminary OAG's audit findings reviewed in May 2005, and a review of the final recommendations contained in the Audit of the Pharmacare Program, to ensure an effective, efficient, and accountable publicly funded drug benefit program. The strategic direction for Pharmacare will include specific objectives with targets that are measurable, clear policy goals/objectives for all aspects of core Pharmacare services, and policies and procedures that support the key Pharmacare outcomes. Further, the Department will continue to improve management practices with the development of a performance measurement system to ensure timely and appropriate program monitoring, evaluation, and risk assessment to implement corrective action when necessary based on evaluation results.

In order to complement the program and evaluation practices, a process is being developed and implemented to identify in a timely manner, the degrees of risks associated with each aspect of the legislation, regulations, and policies for the publicly funded drug benefit program. The Department will also establish a Committee to monitor and evaluate progress on the implementation of the strategic plan.

The Department will also ensure that Manitoba Health's annual reports provide information on Pharmacare that is consistent with Manitoba Finance's Departmental Annual Reports Instructions and consistent with the CCAF's Principles of Performance Reporting.

Finally, the Department is committed to the development and/or application of learning from federal/provincial/territorial collaborative efforts including the National Pharmaceutical Strategy and Best Practice Utilization initiatives to promote cost effective drug use and system efficiency.

Appendix A

GLOSSARY OF TERMS

Bulletin	Once drugs have received approval, from the Minister of Health, for addition or deletion from the Formulary, Manitoba Health is responsible for updating the listing of approved drugs on the Formulary. The listing is updated, via a Manitoba Drug Benefits and Interchangeability Formulary Amendments Bulletin (Bulletin) approximately every three to four months. These Bulletins are posted on the Manitoba Health website and sent to pharmacies and physicians.
CCAF	A Canadian research and educational Foundation dedicated to building knowledge for meaningful accountability and effective governance. CCAF's mission is to provide exemplary thought leadership and to build both knowledge and capacity for effective governance and meaningful accountability, management and audit. The focus for, and beneficiary of, CCAF's work is the public sector.
Canadian Council of Legislative Auditors (CCOLA)	The Canadian Council of Legislative Auditors (CCOLA) is an organization devoted to sharing information and supporting the continued development of auditing methodology, practices and professional development. CCOLA's membership consists of the provincial Auditors General or Provincial Auditors of the Canadian provinces and the federal Auditor General.
Common Drug Review (CDR)	The Common Drug Review (CDR) is a single process for reviewing new drugs and providing Formulary listing recommendations to participating publicly-funded federal, provincial and territorial drug benefit plans in Canada. All jurisdictions are participating except Quebec. The CDR consists of: • a systematic review of the available clinical evidence and a review of the pharmacoeconomic data for the drug; and • a listing recommendation made by the Canadian Expert Drug Advisory Committee (CEDAC).
Dispensing Fee	Refers to the components that comprise the cost to dispense a prescribed drug by a pharmacist. The dispensing or prescribing fee charged by a pharmacist is to cover the costs of staffing, store operations and overhead, preparing and dispensing prescriptions, assuring appropriate use of medication, and provide a reasonable profit.

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Drug Identification Number (DIN)	A registration number that the Health Protection Branch of Health Canada assigns to each prescription and non-prescription drug product marketed under the Food and Drugs Regulations. The DIN is assigned using information in the following areas: manufacturer of the product; active ingredient(s); strength of active ingredient(s); pharmaceutical dosage form; brand/trade name; and route of administration.
Drug Product	A particular presentation of a medicine characterized by its pharmaceutical dosage form and the strength of the active ingredient(s).
Drug Product, Existing	An existing drug product is a DIN for which a benchmark price has been established in accordance with the Board's Guidelines.
Drug Product, New	A new drug product is one for which the introductory price is under review. Patented drug products are considered new in the year during which they are first introduced on the market in Canada or the year they receive their first patent(s) if previously marketed. For price review purposes, new drug products for a given year are those introduced between December 1, of the previous year and November 30, of the reporting year. Because of the filing requirements under the Patented Medicines Regulations and the manner of calculating benchmark prices, drug products introduced in December are considered to have been introduced in the following year.
Drug Program Information Network (DPIN)	Manitoba Health maintains the DPIN computer system - an online, real time computer network system which records and assesses prescriptions at the time they are dispensed. DPIN is linked to all pharmacies in Manitoba. DPIN was established in 1994 as one of the first integrated, real time Pharmacare management systems, and is still one of the most comprehensive in use nationally.
Exception Drug Program (EDP)	When a drug is not listed on Part 1 or Part 2, a request for Exception Drug Status (EDS) coverage will be considered under Part 3 for each individual circumstance.
Formulary	The Manitoba Drug Benefits and Interchangeability Formulary lists therapeutically effective drugs of proven high quality that have been approved as eligible benefits under the Pharmacare drug benefit program. It also includes a list of interchangeable drugs - drugs that are chemically and therapeutically equivalent. It is compiled with the advice of the Manitoba Drug Standards and Therapeutics Committee, assisted by Manitoba Health staff and outside consultants. The Minister of Health gives the final approval for benefits under the Pharmacare drug benefit program. Updates to the Manitoba Formulary are made available every three to four

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	months by bulletin and via Website. Copies of the Manitoba Formulary and the updates are also available at Statutory Publications, 200 Vaughan Street, Winnipeg, Manitoba, R3C 1T5. Each new Formulary has three components: a new Bulletin, a revised Prescription Drugs Cost Assistance Act, and a revised Manitoba Drug Interchangeability Formulary.
Generic Product	A drug product with the same active ingredient, strength and dosage of a brand name drug product.
Health Study Group (HSG)	A study group within CCOLA. The Study Group's purpose is to assist Canadian Legislative Auditors to assume their respective responsibilities with regards to identify and undertake concurrent health audits in areas of strategic importance.
Manitoba College of Physicians and Surgeons (MCPS)	The College's mandate is to protect the public as consumers of medical care and promote the safe and ethical delivery of quality medical care by physicians in Manitoba. This broad mandate is achieved through pursuit of the following goals: • Autonomous self-regulation of the medical profession; • Safe and ethical medical care; • Leadership for quality care; • Public confidence in the medical profession; • Provision of resources to physicians for advice on ethics, standards and quality issues.
Manitoba Drug Standards and Therapeutics Committee (MDSTC)	The Manitoba Drug Standards and Therapeutic Committee (MDSTC) includes two physicians and three pharmacists. Committee members make recommendations on drug interchangeability and on the therapeutic and economic value of drug benefits. Nominations for committee membership are provided by the College of Physicians and Surgeons of Manitoba, the Manitoba Medical Association, Manitoba Pharmaceutical Association and the University of Manitoba. The Manitoba Formulary review committee has these objectives: • To assist Manitoba Health in determining which drugs will be provided to Manitobans by government programs; • To assist Manitoba Health in determining which drugs and drug products are interchangeable; • To assist Manitoba Health in assuring that government drug benefits are rational and cost effective; • To assist Manitoba Health in addressing other drug utilization issues.

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(cont'd.)

Manitoba Pharmaceutical Association (MPhA)	An autonomous, self-regulating body whose purpose is to protect the public interest in the area of pharmaceutical practice. To maintain that protection, MPhA has been granted powers under The Pharmaceutical Act to: • License; • Discipline; • Develop, maintain, and monitor standards of practice; • Administer all other requirements of The Pharmaceutical Act. The MPhA officially represents the pharmacists of Manitoba in all areas relating to professional practice.
Medicine	Any substance or mixture of substances made by any means, whether produced biologically, chemically, or otherwise, that is applied or administered in vivo in humans or in animals to aid in the diagnosis, treatment, mitigation or prevention of disease, symptoms, disorders, abnormal physical states, or modifying organic functions in humans and or animals, however administered. For greater certainty, this definition includes vaccines, topical preparations, anesthetics and diagnostic products used in vivo, regardless of delivery mechanism (e.g., transdermal, capsule form, injectable, inhaler, etc.). This definition excludes medical devices, in vitro diagnostic products and disinfectants that are not used in vivo.
Part 1, 2, 3 Drugs	The Pharmacare drug benefits list (Formulary) is divided into three parts: • Part 1 includes drug products that are eligible for Pharmacare benefits under all prescribed circumstances. • Part 2 includes drug products that are eligible for Pharmacare benefits only when prescribed for certain terms and conditions indicated. • When a drug is not listed on Part 1 or Part 2, a request for Exception Drug Status (EDS) coverage will be considered under Part 3 for each individual circumstance.
Patent	An instrument issued by the Commissioner of Patents in the form of letters patent for an invention that provides its holder with a monopoly limited in time, for the claims made within the patent. A patent gives its holder and its legal representatives, the exclusive right of making, constructing and using the invention and selling it to others to be used.

Appendix A
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Patented Medicine Price Index (PMPI)	The PMPI has been developed by the PMPRB as a measure of average year-over-year change in the transaction prices of patented drug products sold in Canada, based on the price and sales information reported by patentees.
Patented Medicine Prices Review Board (PMPRB)	The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body established by Parliament in 1987 under The Patent Act (Act). The Minister of Health for Canada is responsible for the pharmaceutical provisions of the Act. Although the PMPRB is part of the Health Portfolio, it carries out its mandate at arms-length from the Minister of Health. It also operates independently of other bodies such as Health Canada, which approves drugs for safety and efficacy, and public drug plans, which approve the listing of drugs on their respective formularies for reimbursement purposes.
Pharmacare	A drug benefit program for any Manitoban, regardless of age, whose income is seriously affected by high prescription drug costs.
Provincial Drug Program (PDP)	The operating section of the Manitoba Department of Health (Manitoba Health) with responsibility for administering the Pharmacare Program within Manitoba.

Appendix B

CANADIAN COUNCIL OF LEGISLATIVE AUDITORS-HEALTH STUDY GROUP AUDIT OBJECTIVES AND CRITERIA

The audit objectives used were jointly developed by the legislative audit offices in Canada. As each jurisdiction performed their audit independently, not all objectives and criteria were used in all jurisdictions. There may also be some variation in the wording of specific objectives and criteria between jurisdictions.

Program Management

To assess whether Manitoba Health had adequate procedures in place to manage the performance of Pharmacare.

The criteria that we used to assess this objective are:

- The objectives of the program should encompass the entire program mission. They should be well defined, measurable and periodically reviewed;
- Adequate performance information should be available to measure whether program's mission statement and objectives are being achieved;
- The organization should have adequate standards to monitor and evaluate the program's performance;
- There should be regular evaluation of key aspects of the program's performance and corrective action taken when necessary; and
- Adequate procedures should be in place to ensure compliance with legislation and policies and to take corrective action when necessary.

Drug selection and cost

To assess whether Manitoba Health had adequate procedures in place to ensure resources were managed with due care for cost effectiveness.

The criteria that we used to assess this objective are:

- Drugs to be listed should be properly assessed to ensure they are cost-effective;
- Drugs listed should be regularly evaluated to determine whether they should be retained, deleted or restricted in their use, and corrective action is taken when necessary;
- Drugs under assessment that have the potential for significant cost savings or avoidance should be fast-tracked for inclusion in the list;
- There should be policies and processes in place to ensure that listed drugs and pharmacy services are acquired at the lowest possible cost (including use of competitive processes, generic drugs, and volume discounts);
- Commercial marketing practices should be followed-up to see if they have an impact on the drug/ pharmacare program and strategies; and
- Prices of drugs should be followed-up and analyzed and, if necessary, audited.

Appendix B
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Drug use

To assess whether Manitoba Health monitored the quality and relevance of drug use and encouraged appropriate and economical practices.

The criteria that we used to assess this objective are:

- Prescribing practices should be monitored to assess and, to the extent practical, determine whether they are appropriate and economical;
- Procedures should be in place to encourage improved physician prescribing practices; and
- Procedures should be in place to monitor and analyze drug use, and take corrective action where necessary (over prescribing and potential drug interaction, etc.).

Reporting to the Legislature

To assess whether there was adequate reporting on the pharmacare program's performance and whether reports to the Legislature were prepared in the prescribed time period.

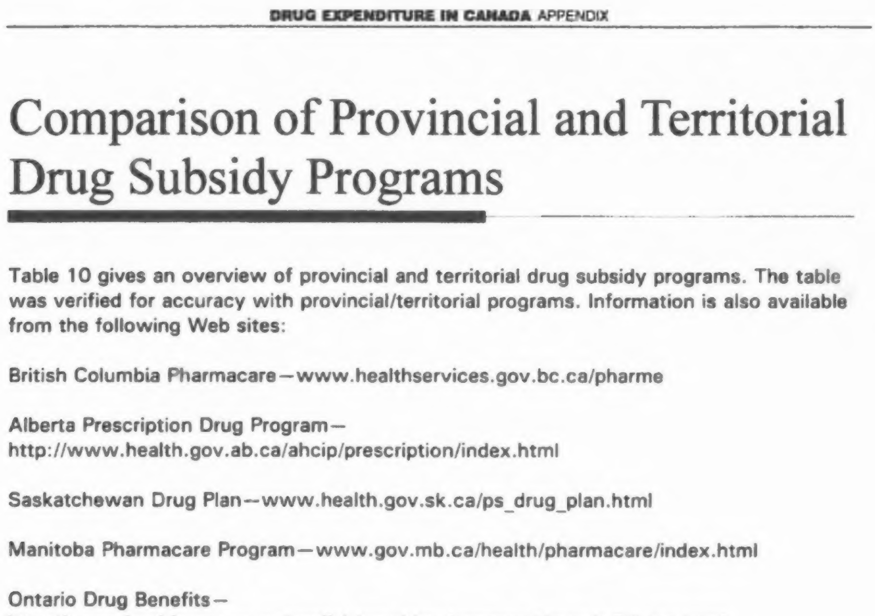
The criteria that we used to assess this objective are:

- The reported information should:
    - focus on the essential aspects of performance;
    - make mention of the future and also the past;
    - explain key risks;
    - explain the main considerations regarding capacity;
    - explain any other essential factors related to performance;
    - integrate financial information with non-financial information;
    - present comparative information;
    - present credible information fairly interpreted; and
    - disclose the basis for reporting.
- The reported information should be presented to parliament/legislature in the prescribed timeframe.

Appendix C

COMPARISON OF PROVINCIAL AND TERRITORIAL DRUG SUBSIDY PROGRAMS

Source: Drug Expenditure in Canada 1985 - 2004 - CIHI



Comparison of Provincial and Territorial Drug Subsidy Programs

Table 10 gives an overview of provincial and territorial drug subsidy programs. The table was verified for accuracy with provincial/territorial programs. Information is also available from the following Web sites:

British Columbia Pharmacare—www.healthservices.gov.bc.ca/pharme

Alberta Prescription Drug Program—
http://www.health.gov.ab.ca/ahcip/prescription/index.html

Saskatchewan Drug Plan—www.health.gov.sk.ca/ps_drug_plan.html

Manitoba Pharmacare Program—www.gov.mb.ca/health/pharmacare/index.html

Ontario Drug Benefits—
http://www.health.gov.on.ca/english/providers/program/drugs/odbf_mn.html

Régime général d'assurance-médicaments du Québec (RGAM)—
http://www.ramq.gouv.qc.ca/en/citoyens/assurancemedicaments/index.shtml

New Brunswick Prescription Drug Program—http://www.gnb.ca/0212/intro-e.asp

Nova Scotia Pharmacare—
http://www.gov.ns.ca/health/pharmacare/default.htm

Prince Edward Island Pharmacy Services —
www.gov.pe.ca/infopei/Government/GovInfo/Health/Pharmacy_Services

Newfoundland and Labrador Prescription Drug Program—
www.gov.nf.ca/health/nlpdp

Yukon Pharmacare—www.hss.gov.yk.ca/prog/hs/insured/pharmacare.html

Northwest Territories—www.hlthss.gov.nt.ca/content/About_HSS/about_index.htm

Nunavut Planning Commission—
http://www.gov.nu.ca/hsssite/hssmain.shtml

Appendix C
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Table 10—Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004

Province Territory	Program Plan	Beneficiary	Premium	Deductible	Co-Pay	Maximum Annual Co-Pay
British Columbia	Fair PharmaCare	All families in which one or more family members were born before 1940 and are not covered by other plans	None	Based on family net income: $0 <$33K 1% $33K to $50K 2% >$50K	PharmaCare pays 75%	1.25% <$33K 2% $33K to $50K 3% >$50K
		Families in which all family members were born after 1940 and are not covered by other plans	None	Based on family net income: $0 <$15K 2% $15K to $30K 3% >$30K	PharmaCare pays 70%	2% <$15K 3% $15K to $30K 4% >$30K
	PharmaCare Plan B	Residents of Long Term Care facilities	None	None	None	N/A
	PharmaCare Plan C	BC Benefits Recipients	None	None	None	N/A
	PharmaCare Plan D	Cystic Fibrosis Patients	None	None	None	N/A
	PharmaCare Plan F	Severely-Handicapped Children-At-Home Program	None	None	None	N/A
	PharmaCare Plan G	Mental Health Centre Clients	None	None	None	N/A
Alberta	Seniors	Seniors and eligible dependants	None	None	30% of prescription to a max of $25.00 per prescription plus additional cost if higher-cost-product is selected	N/A
	Widows	Residents aged 55 to 64 who qualify for Alberta Widows' Pension and eligible dependants	None	None	30% of prescription to a max of $25.00 per prescription plus additional cost if higher-cost-product is selected	N/A

Appendix C
(cont'd.)

Table 10 – Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004

Province/ Territory	Program/Plan	Beneficiary	Premium	Deductible	Co-Pay	Maximum Annual Co-Pay
British Columbia	Fair PharmaCare	All families in which one or more family members were born before 1940 and are not covered by other plans	None	Based on family net income: $0 < $33K 1% $33K to $50K 2% > $50K	PharmaCare pays 75%	1.25% < $33K 2% $33K to $50K 3% > $50K
		Families in which all family members were born after 1940 and are not covered by other plans	None	Based on family net income: $0 < $15K 2% $15K to $30K 3% > $30K	PharmaCare pays 70%	2% < $15K 3% $15K to $30K 4% > $30K
	PharmaCare Plan B	Residents of Long Term Care facilities	None	None	None	N/A
	PharmaCare Plan C	BC Benefits Recipients	None	None	None	N/A
	PharmaCare Plan D	Cystic Fibrosis Patients	None	None	None	N/A
	PharmaCare Plan F	Severely-Handicapped Children-At-Home Program	None	None	None	N/A
	PharmaCare Plan G	Mental Health Centre Clients	None	None	None	N/A
Alberta	Seniors	Seniors and eligible dependants	None	None	30% of prescription to a max of $25.00 per prescription plus additional cost if higher-cost product is selected	N/A
	Widows	Residents aged 55 to 64 who qualify for Alberta Widows' Pension and eligible dependants	None	None	30% of prescription to a max of $25.00 per prescription plus additional cost if higher-cost product is selected	N/A

Appendix C
(cont'd.)

Table 10—Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

Province/Territory	Program Plan	Beneficiary	Premium	Deductible	Co-Pay	Maximum Annual Co-Pay
Alberta (cont'd)	Palliative	Palliative residents treated at home	None	None	30% of prescription to a max of $25.00 per prescription plus additional cost if higher-cost-product is selected	The maximum amount palliative patients pay out-of-pocket is $1,000
	Group 1	A universal plan available to all residents under the age of 65	Quarterly (3-month) rate is $61.50 for singles and $123 for families. Subsidized rates are available at $43.05 for singles and $86.10 for families.	None	30% of prescription to a max of $25.00 per prescription plus additional cost if higher-cost-product is selected	N/A
	Province Wide Services	Residents with specific conditions may be eligible for high-cost drugs, mostly transplant and HIV drugs	None	None	None	N/A
	Income Support	Residents receiving social assistance and eligible dependants	None	None	$2.00 per prescription for first three prescriptions each month	N/A
	Assured Income for the Severely Handicapped (AISH)	Residents receiving AISH (an income support program for adults with a permanent disability that severely impairs their ability to earn a living) and eligible dependants	None	None	$2.00 per prescription for first three prescriptions each month	N/A
	Alberta Adult Health Benefit	Qualified clients leaving Income Support for work	None	None	$2.00 per prescription for first three prescriptions each month	N/A
	Alberta Child Health Benefit	Children in low-income families	None	None	None	N/A

Appendix C
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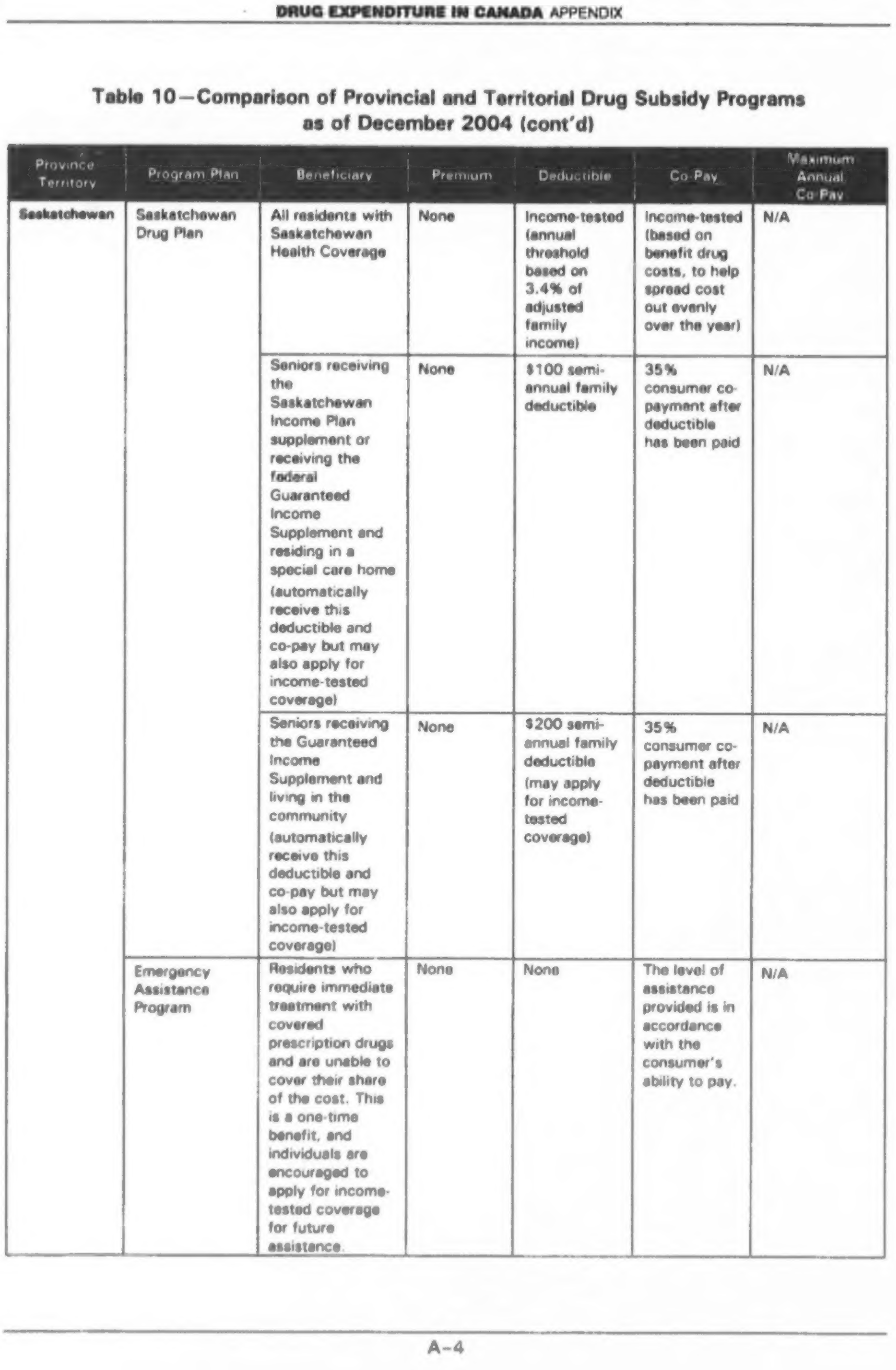

Table 10—Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

Province Territory	Program Plan	Beneficiary	Premium	Deductible	Co-Pay	Maximum Annual Co-Pay
Saskatchewan	Saskatchewan Drug Plan	All residents with Saskatchewan Health Coverage	None	Income-tested (annual threshold based on 3.4% of adjusted family income)	Income-tested (based on benefit drug costs, to help spread cost out evenly over the year)	N/A
		Seniors receiving the Saskatchewan Income Plan supplement or receiving the federal Guaranteed Income Supplement and residing in a special care home (automatically receive this deductible and co-pay but may also apply for income-tested coverage)	None	$100 semi-annual family deductible	35% consumer co-payment after deductible has been paid	N/A
		Seniors receiving the Guaranteed Income Supplement and living in the community (automatically receive this deductible and co-pay but may also apply for income-tested coverage)	None	$200 semi-annual family deductible (may apply for income-tested coverage)	35% consumer co-payment after deductible has been paid	N/A
	Emergency Assistance Program	Residents who require immediate treatment with covered prescription drugs and are unable to cover their share of the cost. This is a one-time benefit, and individuals are encouraged to apply for income-tested coverage for future assistance.	None	None	The level of assistance provided is in accordance with the consumer's ability to pay.	N/A

Appendix C
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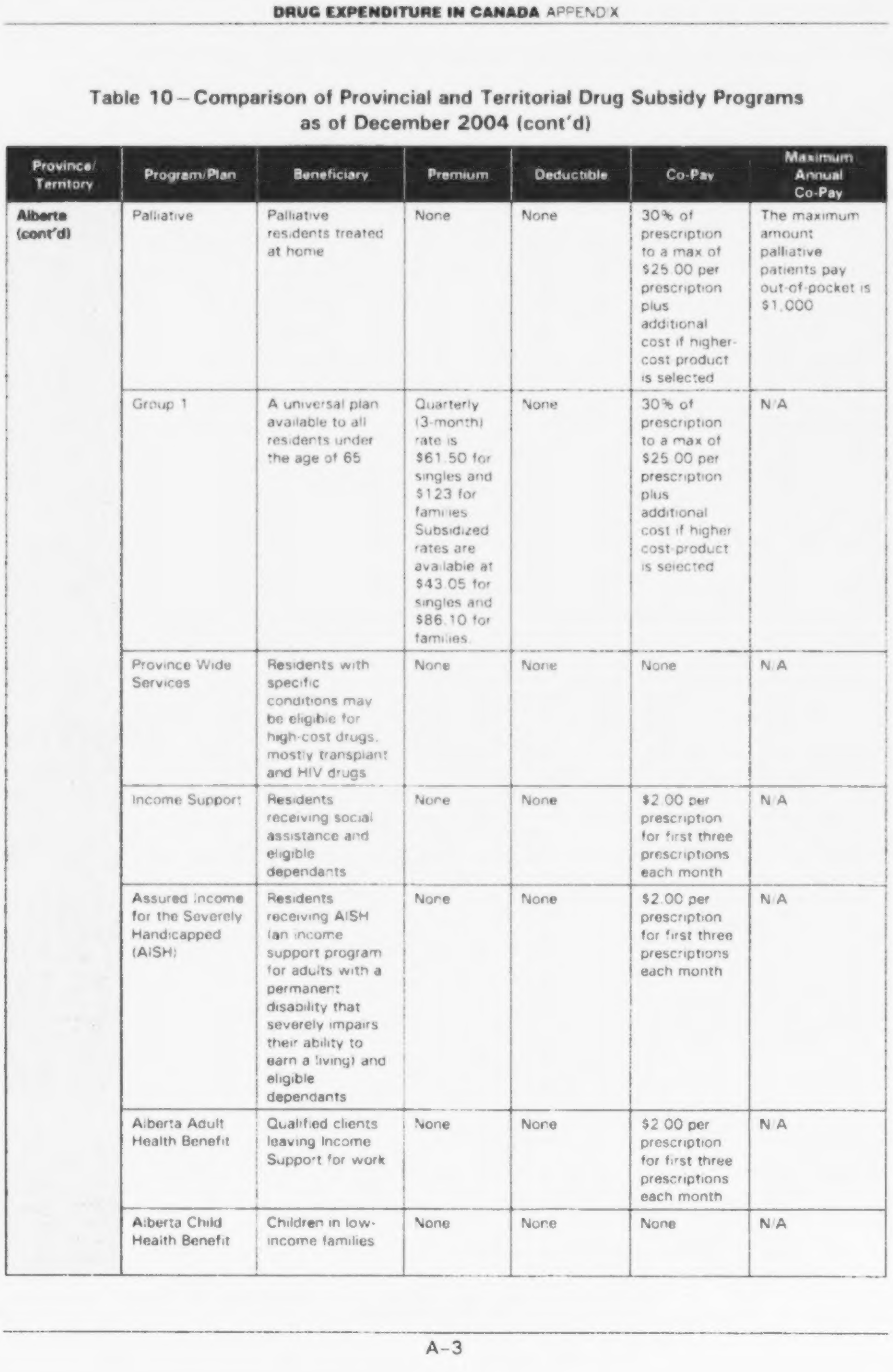


Table 10 – Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

Province/ Territory	Program/Plan	Beneficiary	Premium	Deductible	Co-Pay	Maximum Annual Co-Pay
Alberta (cont'd)	Palliative	Palliative residents treated at home	None	None	30% of prescription to a max of $25.00 per prescription plus additional cost if higher-cost product is selected	The maximum amount palliative patients pay out-of-pocket is $1,000
	Group 1	A universal plan available to all residents under the age of 65	Quarterly (3-month) rate is $61.50 for singles and $123 for families. Subsidized rates are available at $43.05 for singles and $86.10 for families.	None	30% of prescription to a max of $25.00 per prescription plus additional cost if higher cost-product is selected	N/A
	Province Wide Services	Residents with specific conditions may be eligible for high-cost drugs, mostly transplant and HIV drugs	None	None	None	N/A
	Income Support	Residents receiving social assistance and eligible dependants	None	None	$2.00 per prescription for first three prescriptions each month	N/A
	Assured Income for the Severely Handicapped (AISH)	Residents receiving AISH (an income support program for adults with a permanent disability that severely impairs their ability to earn a living) and eligible dependants	None	None	$2.00 per prescription for first three prescriptions each month	N/A
	Alberta Adult Health Benefit	Qualified clients leaving Income Support for work	None	None	$2.00 per prescription for first three prescriptions each month	N/A
	Alberta Child Health Benefit	Children in low-income families	None	None	None	N/A

Appendix C
(cont'd.)

Table 10 – Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

Province/ Territory	Program/Plan	Beneficiary	Premium	Deductible	Co-Pay	Maximum Annual Co-Pay
Saskatchewan	Saskatchewan Drug Plan	All residents with Saskatchewan Health Coverage	None	Income tested (annual threshold based on 3.4% of adjusted family income)	Income tested (based on benefit drug costs, to help spread cost out evenly over the year)	N/A
		Seniors receiving the Saskatchewan Income Plan supplement or receiving the federal Guaranteed Income Supplement and residing in a special care home (automatically receive this deductible and co-pay but may also apply for income tested coverage)	None	$100 semi-annual family deductible	35% consumer co-payment after deductible has been paid	N/A
		Seniors receiving the Guaranteed Income Supplement and living in the community (automatically receive this deductible and co-pay but may also apply for income tested coverage)	None	$200 semi-annual family deductible (may apply for income tested coverage)	35% consumer co-payment after deductible has been paid	N/A
	Emergency Assistance Program	Residents who require immediate treatment with covered prescription drugs and are unable to cover their share of the cost. This is a one time benefit, and individuals are encouraged to apply for income tested coverage for future assistance	None	None	The level of assistance provided is in accordance with the consumer's ability to pay.	N/A

Appendix C
(cont'd.)

Table 10—Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

Province Territory	Program Plan	Beneficiary	Premium	Deductible	Co-Pay	Maximum Annual Co-Pay
Saskatchewan (cont'd)	Family Health Benefits	Eligibility is established by the Department of Social Services, based on the number of children in the family and the family's annual income. (automatically receive this deductible and co-pay but may also apply for income-tested coverage)	None	$100.00 semi-annual family deductible	No charge for benefit prescriptions for children; 35% consumer co-payment after deductible has been paid for adult benefit prescriptions	N/A
	Supplementary Health	Persons nominated by Saskatchewan Social Services for special coverage, including persons on Social Assistance, wards, inmates, etc.	None	None	Up to $2.00 per prescription (some drugs covered at no charge; individuals under 18 and certain other categories receive benefit prescriptions at no charge)	N/A
	Saskatchewan Aids to Independent Living (SAIL)	Persons registered under the following SAIL programs receive Formulary and approved non-Formulary drugs at no charge: Paraplegia Program, Cystic Fibrosis Program, and Chronic End Stage Renal Disease Program	None	None	None	N/A
	Drug Plan Palliative Care Program	Residents who are in the late stages of a terminal illness	None	None	None	N/A

Appendix C
(cont'd.)

Table 10—Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

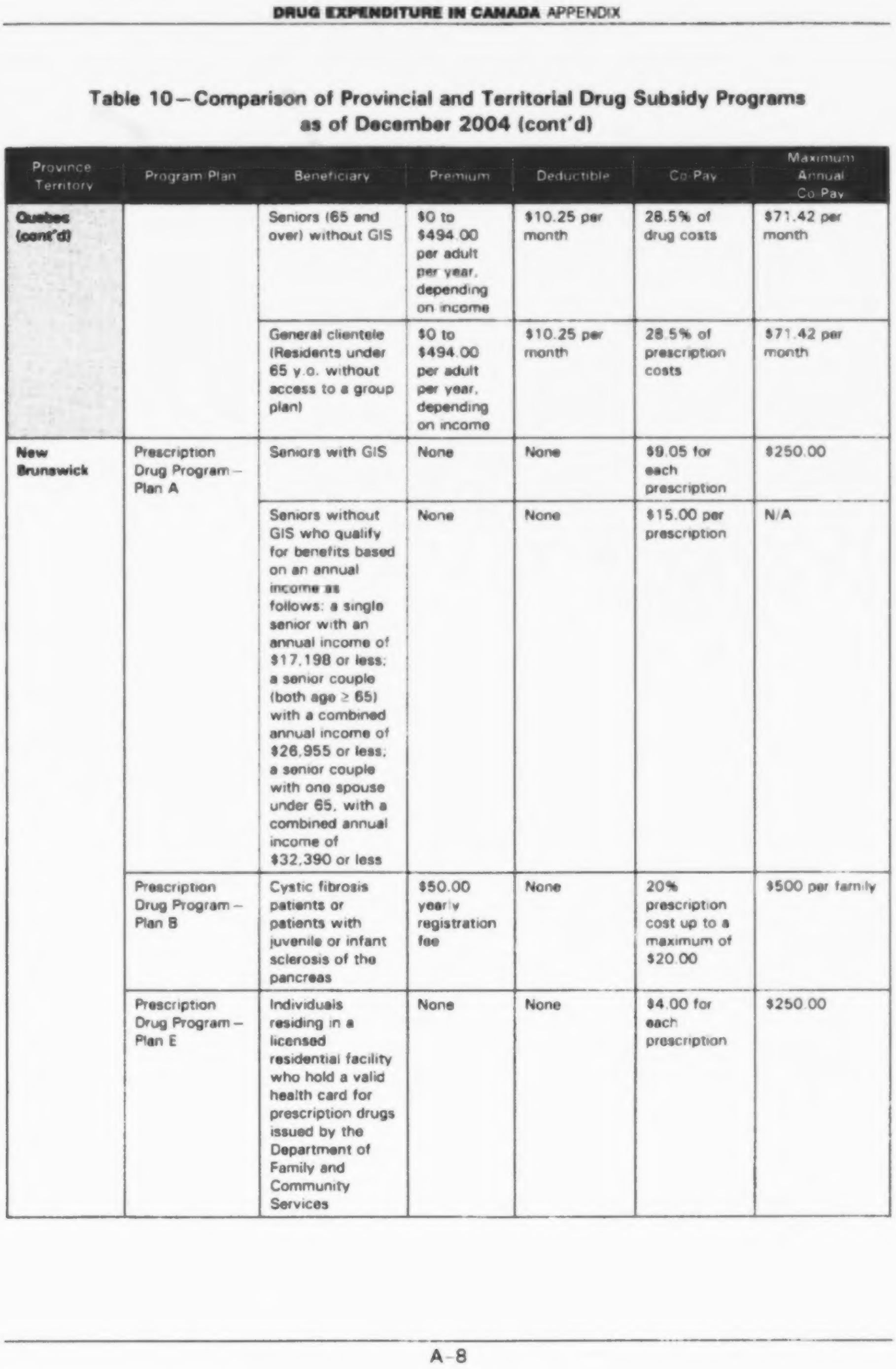
Province Territory	Program Plan	Beneficiary	Premium	Deductible	Co Pay	Maximum Annual Co Pay
Manitoba	Pharmacare	All provincial residents who are eligible for benefits under Manitoba Health's Provincial Drug Program, with the exception of residents covered under other Statutes.	None	Based on total Adjusted family income; 2.32% of < = $15,000; 3.48% of $15,000-$40,000; 4% of $40,000-$75,000; 5% of > $75,000; credit of $3,000 for spouse and dependent under 18 years; minimum of $100 deductible is applicable	None	N/A
	Family Services	Individual Manitobans that are receiving drug benefits pursuant to the Social Assistance Health Services Drug Program.	None	None	None	N/A
	Personal Care Home	Manitoba residents of Personal Care Homes.	None	None	None	N/A
	Palliative Care	Residents who are terminally ill and wish to remain at home	None	None	None	N/A

Appendix C
(cont'd.)

Table 10—Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

Province/Territory	Program/Plan	Beneficiary	Premium	Deductible	Co-Pay	Maximum Annual Co-Pay
Ontario	Ontario Drug Benefit Program	Seniors (aged 65 and older)	None	$100.00	After deductible, up to $6.11 per prescription	N/A
		Residents of long-term care facilities	None	None	Up to $2.00 per prescription	N/A
		Residents of Homes for Special Care	None	None	Up to $2.00 per prescription	N/A
		Residents receiving professional services under the Home Care program	None	None	Up to $2.00 per prescription	N/A
		Residents receiving social assistance	None	None	Up to $2.00 per prescription	N/A
	Trillium Drug Program	Residents with high drug costs in relation to income	None	Income-based	Up to $2.00 per prescription	N/A
	Special Drugs Program	Residents with valid Ontario Health insurance. Coverage is product specific for a limited number of diseases or conditions.	None	None	None	N/A
Quebec	Régime général d'assurance-médicaments du Québec (RGAM)	Employment assistance (welfare) recipients (EAR) and other holders of a carnet de réclamation (claim slip)	None	$8.33 per month	25% of prescription costs	$16.66 per month (No deductibles and copay for EAR with severe employment constraints)
		Seniors (65 and over) receiving at least 94 % of the maximum GIS	None	$8.33 per month	25% of prescription costs	$16.66 per month
		Seniors (65 and over) receiving less than 94 % of the maximum GIS (partial GIS)	$0 to $494.00 per adult per year, depending on income	$10.25 per month	28.5% of prescription costs	$46.67 per month

Appendix C
(cont'd.)



DRUG EXPENDITURE IN CANADA APPENDIX

Table 10—Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

Province Territory	Program Plan	Beneficiary	Premium	Deductible	Co-Pay	Maximum Annual Co-Pay
Quebec (cont'd)		Seniors (65 and over) without GIS	$0 to $494.00 per adult per year, depending on income	$10.25 per month	28.5% of drug costs	$71.42 per month
		General clientele (Residents under 65 y.o. without access to a group plan)	$0 to $494.00 per adult per year, depending on income	$10.25 per month	28.5% of prescription costs	$71.42 per month
New Brunswick	Prescription Drug Program – Plan A	Seniors with GIS	None	None	$9.05 for each prescription	$250.00
		Seniors without GIS who qualify for benefits based on an annual income as follows: a single senior with an annual income of $17,198 or less; a senior couple (both age ≥ 65) with a combined annual income of $26,955 or less; a senior couple with one spouse under 65, with a combined annual income of $32,390 or less	None	None	$15.00 per prescription	N/A
	Prescription Drug Program – Plan B	Cystic fibrosis patients or patients with juvenile or infant sclerosis of the pancreas	$50.00 yearly registration fee	None	20% prescription cost up to a maximum of $20.00	$500 per family
	Prescription Drug Program – Plan E	Individuals residing in a licensed residential facility who hold a valid health card for prescription drugs issued by the Department of Family and Community Services	None	None	$4.00 for each prescription	$250.00

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Appendix C
(cont'd.)

Table 10—Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

Province Territory	Program Plan	Beneficiary	Premium	Deductible	Co Pay	Maximum Annual Co-Pay
New Brunswick (cont'd)	Prescription Drug Program—Plan F	Individuals holding a valid health card for prescription drugs issued by the Department of Family and Community Services	None	None	$4.00 per prescription for adults (18 and over) and $2.00 for children (under 18 years)	$250.00 per family
	Prescription Drug Program—Plan G	Special needs children and children under the care of the Minister of Family and Community Services	None	None	None	N/A
	Prescription Drug Program—Plan H	Residents in possession of a prescription written by a neurologist for the medications Avonex, Rebif, Betaseron or Copaxone are eligible to apply for assistance	$50.00 yearly registration fee	None	Income-tested Ranges from 0-100%	N/A
	Prescription Drug Program—Plan R	Organ transplant recipients who are registered and qualify with the NBPDP	$50.00 yearly registration fee	None	20% prescription cost up to a maximum of $20.00	$500.00 per family
	Prescription Drug Program—Plan T	Individuals with growth hormone deficiency who are registered and qualify with the NBPDP	$50.00 yearly registration fee	None	20% prescription cost up to a maximum of $20.00	$500.00 per family
	Prescription Drug Program—Plan U	Individuals who are HIV positive and are registered with the NBPDP	$50.00 yearly registration fee	None	20% prescription cost up to a maximum of $20.00	$500.00 per family
	Prescription Drug Program—Plan V	Individuals who reside in a registered nursing home	None	None	None	N/A

Appendix C
(cont'd.)

Table 10—Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

Province/ Territory	Program Plan	Beneficiary	Premium	Deductible	Co-Pay	Maximum Annual Pay
Nova Scotia	Seniors Pharmacare Program	Seniors (65 and older) receiving GIS and covered by MSI (Medical Services Insurance) and not having coverage through Veterans Affairs Canada, First Nations and Inuit Health, or a private drug plan	None	None	33% prescription cost ($3.00 minimum and $30.00 maximum)	$350.00
		Seniors (65 and older) not receiving GIS and covered by MSI (Medical Services Insurance) and not having coverage through Veterans Affairs Canada, First Nations and Inuit Health, or a private drug plan	Up to $390.00 per year	None	33% prescription cost ($3.00 minimum and $30.00 maximum)	$350.00
	Department of Community Services Programs	Eligible clients and their dependents in receipt of Income Assistance, any client and/or dependent having access to another drug plan, be it from a public or private entity, will be required to use that plan and will not be eligible for the Pharmacare program	None	None	All income assistance clients and dependents are required to co-pay a flat fee of $5.00 per prescription, unless the client or dependent is eligible for co-pay exemption	N/A
	Drug Assistance for Cancer Patients	Residents having a gross family income no greater than $15,720 per year, and not eligible for coverage under other drug programs	None	None	None	N/A
	Multiple Sclerosis Drug Funding Assistance	Residents who meet established MS criteria and who do not have other drug coverage	None	None	$9.35 per prescription	N/A

Appendix C
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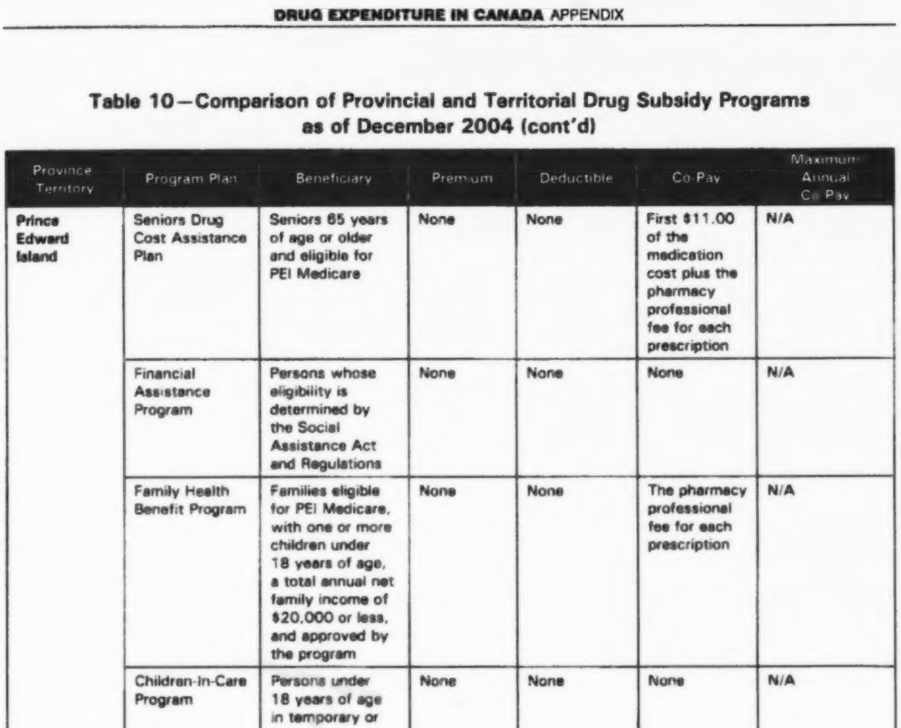


Table 10—Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

Province Territory	Program Plan	Beneficiary	Premium	Deductible	Co Pay	Maximum Annual Co Pay
Prince Edward Island	Seniors Drug Cost Assistance Plan	Seniors 65 years of age or older and eligible for PEI Medicare	None	None	First $11.00 of the medication cost plus the pharmacy professional fee for each prescription	N/A
	Financial Assistance Program	Persons whose eligibility is determined by the Social Assistance Act and Regulations	None	None	None	N/A
	Family Health Benefit Program	Families eligible for PEI Medicare, with one or more children under 18 years of age, a total annual net family income of $20,000 or less, and approved by the program	None	None	The pharmacy professional fee for each prescription	N/A
	Children-In-Care Program	Persons under 18 years of age in temporary or permanent custody of the Director of Child Welfare	None	None	None	N/A
	Diabetes Control Program	Persons with diabetes eligible for PEI Medicare and who are registered with the program	None	None	Insulin: $10.00 per 10mL vial of insulin or box of 1.5 mL insulin cartridges; $20.00 per box of 3.0 mL insulin cartridges. Oral Medications and Urine Testing Materials: $11.00 per prescription.	N/A

Appendix C
(cont'd.)

Table 10—Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

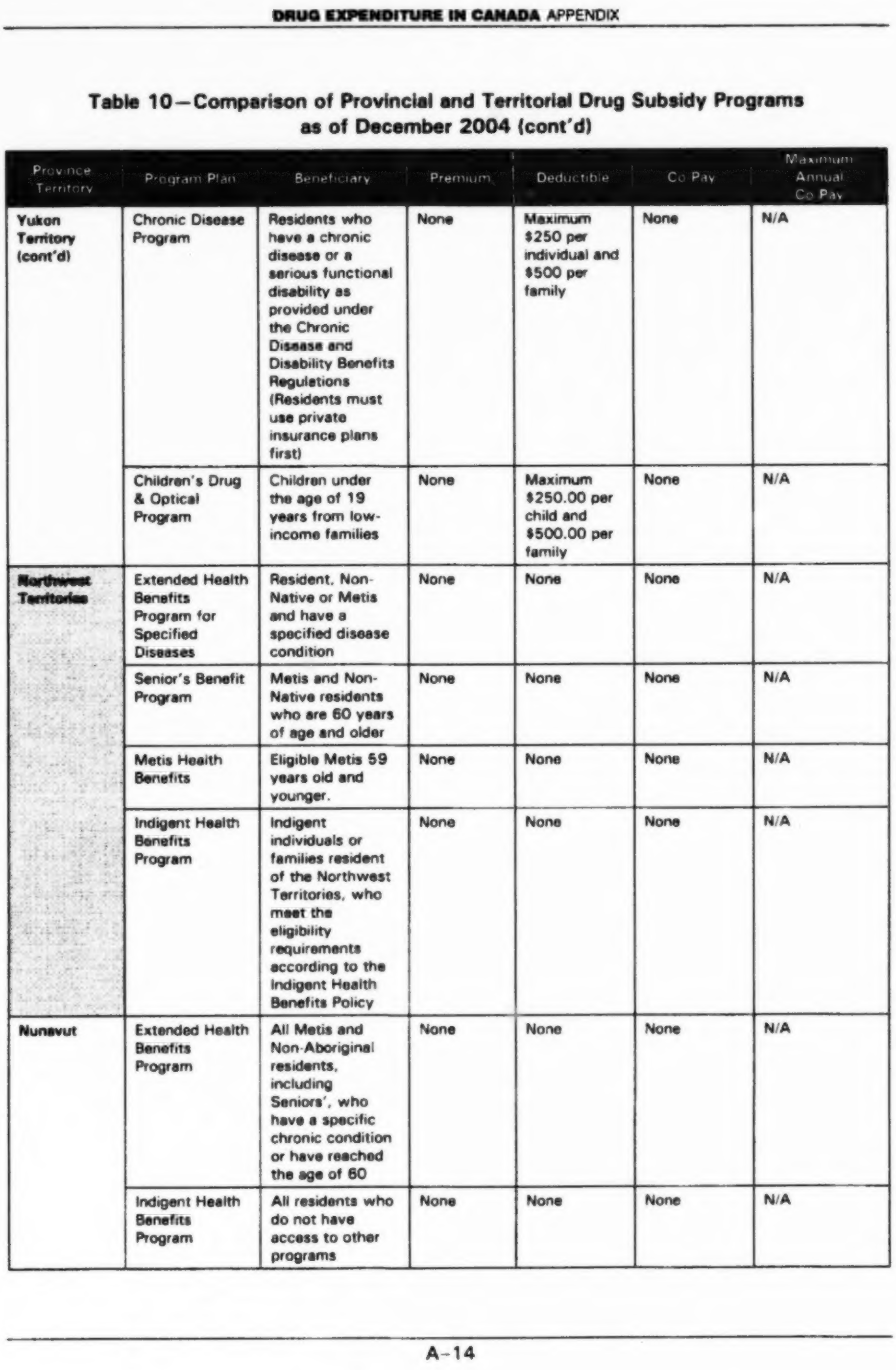
Province Territory	Program Plan	Beneficiary	Premium	Deductible	Co Pay	Maximum Annual Co Pay
Prince Edward Island (cont'd)	Multiple Sclerosis Medications Program	Persons eligible for PEI Medicare, diagnosed with relapsing-remitting or secondary progressive multiple sclerosis, and approved by the program	None	None	Income tested copay plus the pharmacy professional fee for each prescription	N/A
	Remicade and Enbrel Program	Persons eligible for PEI Medicare, diagnosed with severe Rheumatoid Arthritis or Crohn's Disease, and approved by the program.	None	None	Income tested copay plus the pharmacy professional fee for each prescription	N/A
	Sexually Transmitted Diseases (STD) Program	Persons diagnosed with sexually transmitted disease or identified contacts of a person with a sexually transmitted disease	None	None	None	N/A
	Nursing Home and Institutional Pharmacy Programs	Residents in government Manors and private nursing homes eligible for coverage under the Social Assistance Act and Regulations	None	None	None	N/A
	Disease Specific Programs (e.g. AIDS/HIV, Cystic Fibrosis, Growth Hormone, Hepatitis, and Transplant Drug Programs delivered through the Provincial Pharmacy)	Persons diagnosed with specific medical conditions	None	None	None	N/A

Appendix C
(cont'd.)

Table 10—Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

Province Territory	Program Plan	Beneficiary	Premium	Deductible	Co Pay	Maximum Annual Co Pay
Newfoundland and Labrador	The Senior Citizens Drug Subsidy Program	Seniors' (65 and older) who are in receipt of the Guaranteed Income Supplement and who are registered for the Old Age Security benefits	None	None	Mark-up and Professional Fee for identified benefits	N/A
	The Income Support Program	Residents of the province who qualify for full benefit coverage under the Department of Humans Resources and Employment	None	None	None	N/A
		Residents who, due to the high cost of their medications, may qualify for drug card only benefits	None	None	None	N/A
	The Special Needs Program	Residents patients with Cystic Fibrosis or Growth Hormone deficiency	None	None	None, for identified benefits	N/A
Yukon Territory	Pharmacare	Seniors 65 years of age or older (and seniors' spouses aged 60 years and older) registered with Yukon Health Care Insurance Plan (YCHCIP) and not having coverage through First Nations and Inuit Health	None	None	None	N/A

Appendix C
(cont'd.)



DRUG EXPENDITURE IN CANADA APPENDIX

Table 10—Comparison of Provincial and Territorial Drug Subsidy Programs as of December 2004 (cont'd)

Province Territory	Program Plan	Beneficiary	Premium	Deductible	Co Pay	Maximum Annual Co Pay
Yukon Territory (cont'd)	Chronic Disease Program	Residents who have a chronic disease or a serious functional disability as provided under the Chronic Disease and Disability Benefits Regulations (Residents must use private insurance plans first)	None	Maximum $250 per individual and $500 per family	None	N/A
	Children's Drug & Optical Program	Children under the age of 19 years from low-income families	None	Maximum $250.00 per child and $500.00 per family	None	N/A
Northwest Territories	Extended Health Benefits Program for Specified Diseases	Resident, Non-Native or Metis and have a specified disease condition	None	None	None	N/A
	Senior's Benefit Program	Metis and Non-Native residents who are 60 years of age and older	None	None	None	N/A
	Metis Health Benefits	Eligible Metis 59 years old and younger.	None	None	None	N/A
	Indigent Health Benefits Program	Indigent individuals or families resident of the Northwest Territories, who meet the eligibility requirements according to the Indigent Health Benefits Policy	None	None	None	N/A
Nunavut	Extended Health Benefits Program	All Metis and Non-Aboriginal residents, including Seniors', who have a specific chronic condition or have reached the age of 60	None	None	None	N/A
	Indigent Health Benefits Program	All residents who do not have access to other programs	None	None	None	N/A

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Appendix D

PHARMACARE DEDUCTIBLE CALCULATOR

http://www.gov.mb.ca/health/pharmacare/estimator.html

The Pharmacare deductible for the 2005/06 benefit year is calculated based on the following:

- The total income is determined from line 150 of your 2003 Canada Revenue Agency (CRA) *Notice of Assessment;*
- Manitoba Health will add the applicant's total income to the total income of the spouse (if applicable);
- $3,000.00 is subtracted from this total income for one spouse and each dependant under the age of 18 years; and
- This equals to what is referred to as the **Adjusted Total Family Income**.

Adjusted Total Family Income	Pharmacare Deductible Rate
less than or equal to $15,000	2.44%
greater than $15,000 and less than or equal to $40,000	3.65%
greater than $40,000 and less than or equal to $75,000	4.20%
greater than $75,000	5.25%

Excerpt: The Auditor General Act

Audit of operations

14(1) In carrying out his or her responsibilities under this Act, the Auditor General may examine and audit the operations of a government organization with regard to any of the following matters:

(a) whether financial and administrative provisions of Acts, regulations, policies and directives have been complied with;

(b) whether public money has been expended with proper regard for economy and efficiency;

(c) whether the Assembly has been provided with appropriate accountability information;

(d) whether the form and content of financial information documents is adequate and suitable.

Copies of this report may be obtained by contacting:

Office of the Auditor General

500–330 PORTAGE AVENUE
WINNIPEG, MANITOBA CANADA R3C 0C4
PHONE: 204 945 3790 FAX: 204 945 2169
EMAIL: contact@oag.mb.ca
WEBSITE: www.oag.mb.ca

EXECUTIVE MANAGEMENT
Jon Singleton
Bonnie Lysyk

AUDIT PRINCIPAL
John Heke

AUDIT TEAM
Marianne Farag
David Storm
Gord Glesmann
Bradley Keefe
Fraser McLean

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Dr. Anita Kozyrskyj, Ph.D.
Manitoba Centre for
Health Policy

DESKTOP PUBLISHER
Sandra Humbert

COVER DESIGN
Cocoon Branding Inc.

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Office of the Auditor General

500–330 PORTAGE AVENUE

WINNIPEG, MANITOBA CANADA R3C 0C4

PHONE: 204 945 3790 FAX: 204 945 2169

EMAIL: contact@oag.mb.ca

WEBSITE: www.oag.mb.ca

EXECUTIVE MANAGEMENT
Jon Singleton
Bonnie Lysyk

AUDIT PRINCIPAL
John Heke

AUDIT TEAM
Marianne Farag
David Storm
Gord Glesmann
Bradley Keefe
Fraser McLean

ACKNOWLEDGMENTS

Dr. Anita Kozyrskyj, Ph.D.
Manitoba Centre for
Health Policy

DESKTOP PUBLISHER
Sandra Humbert

COVER DESIGN
Cocoon Branding Inc.

Openness Teamwork Professionalism Excellence

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